

EXHIBIT B

Filed with Redactions

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 IN RE: VALSARTAN, § MDL NO. 2875
5 LOSARTAN, AND §
6 IRBESARTAN PRODUCTS § HONORABLE ROBERT B. KUGLER
7 LIABILITY LITIGATION § DISTRICT COURT JUDGE

8 ORAL AND VIDEOTAPED DEPOSITION OF
9 JOHN L. QUICK
10 JANUARY 27, 2022

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13 ORAL AND VIDEOTAPED DEPOSITION OF JOHN L. QUICK,
14 produced as a witness at the instance of the
15 Defendants and duly sworn, was taken in the above
16 styled and numbered cause on Thursday,
17 January 27, 2022, from 9:33 a.m. to 7:00 p.m.,
18 before TAMARA CHAPMAN, CSR, RPR-CRR in and for the
19 State of Texas, reported by computerized stenotype
20 machine, at the offices of Slack Davis Sanger, LLP,
21 6001 Bold Ruler Way, Suite 100, Austin, Texas,
22 pursuant to the Federal Rules of Civil Procedure and
23 any provisions stated on the record herein.
24
25

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES</p> <p>2</p> <p>3 FOR THE PLAINTIFF(S):</p> <p>4 John R Davis</p> <p>5 SLACK DAVIS SANGER, LLP</p> <p>6 6001 Bold Ruler Way, Suite 100</p> <p>7 Austin, Texas 78746</p> <p>8 512-795-8686</p> <p>9 jdavis@slackdavis.com</p> <p>10</p> <p>11 Layne Hilton</p> <p>12 Conlee S Whiteley</p> <p>13 David J Stanoch</p> <p>14 KANNER & WHITELEY, L L C</p> <p>15 701 Camp Street</p> <p>16 New Orleans, Louisiana 70130</p> <p>17 504-524-5777</p> <p>18 lhilton@kanner-law.com</p> <p>19 cwhiteley@kanner-law.com</p> <p>20 dstanoch@kanner-law.com</p> <p>21</p> <p>22 Ruben Honik</p> <p>23 HONIK LLC</p> <p>24 1515 Market Street, Suite 1100</p> <p>25 Philadelphia, Pennsylvania 19102</p> <p>26 267-435-1300</p> <p>27 ruben@honiklaw.co</p> <p>28</p> <p>29 FOR PLAINTIFF MSP RECOVERY CLAIMS, SERIES, LLC:</p> <p>30 Charlie Whorton</p> <p>31 RIVERO MESTRE, LLP</p> <p>32 2525 Ponce De Leon Boulevard, Suite 1000</p> <p>33 Miami, Florida 33134</p> <p>34 305-445-2500</p> <p>35 cwhorton@riveromestre.com</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES</p> <p>2 (Continued)</p> <p>3</p> <p>4 FOR ZHEJIANG HUAHAI PHARMACEUTICAL, CO., LTD., SOLCO</p> <p>5 HEALTHCARE U.S., LLC, AND PRINSTON PHARMACEUTICAL, INC.:</p> <p>6 Seth Goldberg</p> <p>7 DUANE MORRIS, LLP</p> <p>8 30 South 17th Street</p> <p>9 Philadelphia, Pennsylvania 19103</p> <p>10 215-979-1175</p> <p>11 sagoldberg@duanemorris.com</p> <p>12</p> <p>13 Coleen W Hill</p> <p>14 DUANE MORRIS, LLP</p> <p>15 30 South 17th Street</p> <p>16 Philadelphia, Pennsylvania 19103</p> <p>17 215-979-1164</p> <p>18 cwhill@duanemorris.com</p> <p>19</p> <p>20 FOR HUMANA INC. & HUMANA PHARMACY, INC.:</p> <p>21 Megan A Zmick</p> <p>22 FALKENBERG IVES, LLP</p> <p>23 230 W Monroe, Suite 2220</p> <p>24 Chicago, Illinois 60606</p> <p>25 312-566-4808</p> <p>26 maz@falkenbergives.com</p> <p>27</p> <p>28 FOR AUROBINDO PHARMA LTD.:</p> <p>29 Steven N Hunchuck</p> <p>30 John Gisleson</p> <p>31 MORGAN LEWIS</p> <p>32 One Oxford Centre, 32nd Floor</p> <p>33 Pittsburgh, Pennsylvania 15219</p> <p>34 412-560-3300</p> <p>35 steven.hunchuck@morganlewis.com</p> <p>36 john.gisleson@morganlewis.com</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES</p> <p>2 (Continued)</p> <p>3</p> <p>4 FOR TEVA PHARMACEUTICALS USA, INC., TEVA</p> <p>5 PHARMACEUTICAL INDUSTRIES LTD., ACTAVIS PHARMA,</p> <p>6 INC., AND ACTAVIS LLC:</p> <p>7 Nilda Isidro</p> <p>8 Glenn Kerner</p> <p>9 GREENBERG TRAURIG, LLP</p> <p>10 One Vanderbilt Avenue</p> <p>11 New York, New York 10017</p> <p>12 212-801-9200</p> <p>13 isidron@gtlaw.com</p> <p>14 kernerg@gtlaw.com</p> <p>15 Gregory Coates</p> <p>16 GREENBERG TRAURIG, LLP</p> <p>17 500 Campus Drive, Suite 400</p> <p>18 Florham Park, New Jersey 07932</p> <p>19 973-443-3269</p> <p>20 coatesg@gtlaw.com</p> <p>21</p> <p>22 Brian Rubenstein</p> <p>23 GREENBERG TRAURIG, LLP</p> <p>24 1717 Arch Street, Suite 400</p> <p>25 Philadelphia, Pennsylvania 19103</p> <p>26 215-988-7864</p> <p>27 rubensteinb@gtlaw.com</p> <p>28</p> <p>29 Steven M Harkins</p> <p>30 Victoria Davis Lockard</p> <p>31 GREENBERG TRAURIG, LLP</p> <p>32 Terminus 200</p> <p>33 3333 Piedmont Road NE, Suite 2500</p> <p>34 Atlanta, Georgia 30305</p> <p>35 678-553-2100</p> <p>36 harkins@gtlaw.com</p> <p>37 lockardv@gtlaw.com</p> <p>38</p> <p>39 Rosemarie Riddell Bogdan</p> <p>40 MARTIN, HARDING & MAZZOTTI, LLP</p> <p>41 P O Box 15141</p> <p>42 Albany, New York 12212</p> <p>43 518-724-2207</p> <p>44 rosemarie.bogdan@1800law1010.com</p> <p>45</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES</p> <p>2 (Continued)</p> <p>3</p> <p>4 FOR MCKESSON CORPORATION:</p> <p>5 Ellie Norris</p> <p>6 D'Lesli M Davis</p> <p>7 NORTON ROSE FULBRIGHT</p> <p>8 2200 Ross Avenue, Suite 3600</p> <p>9 Dallas, Texas 75201</p> <p>10 214-855-8000</p> <p>11 ellie.norris@nortonrosefulbright.com</p> <p>12 dlesli.davis@nortonrosefulbright.com</p> <p>13</p> <p>14 FOR MAJOR PHARMACEUTICALS:</p> <p>15 Luke Bresnahan</p> <p>16 Daniel T Campbell</p> <p>17 CROWELL & MORING</p> <p>18 1001 Pennsylvania Avenue, NW</p> <p>19 Washington, D.C. 20004</p> <p>20 202-624-2500</p> <p>21 lbresnahan@crowell.com</p> <p>22 dcampbell@crowell.com</p> <p>23</p> <p>24 FOR TORRENT PHARMA INC. & TORRENT PHARMACEUTICALS</p> <p>25 LIMITED:</p> <p>26 Brittney Nagle</p> <p>27 KIRKLAND & ELLIS, LLP</p> <p>28 601 Lexington Avenue</p> <p>29 New York, New York 10022</p> <p>30 212-390-4210</p> <p>31 brittney.nagle@kirkland.com</p> <p>32</p> <p>33 FOR CIGNA CORPORATION, EXPRESS SCRIPTS HOLDING</p> <p>34 COMPANY & EXPRESS SCRIPTS, INC.:</p> <p>35 Sarah L Zimmerman</p> <p>36 Matthew D Knepper</p> <p>37 HUSCH BLACKWELL</p> <p>38 190 Carondelet Plaza, Suite 600</p> <p>39 St Louis, Missouri 63105</p> <p>40 314-480-1500</p> <p>41 sarah.zimmerman@huschblackwell.com</p> <p>42 matt.knepper@huschblackwell.com</p>

<p style="text-align: right;">Page 6</p> <p>1 APPEARANCES (Continued)</p> <p>2</p> <p>3 FOR HETERO LABS LTD: William P Murtha, Jr 4 HILL WALLACK, LLP The Galleria 5 2 Bridge Avenue, Suite 211 Red Bank, New Jersey 07701 6 732-924-8171 wmurtha@hillwallack.com</p> <p>7</p> <p>8 Eric Abraham HILL WALLACK, LLP 9 21 Roszel Road Princeton, New Jersey 08540 10 609-734-6358 eabraham@hillwallack.com</p> <p>11</p> <p>12 FOR CAMBER PHARMACEUTICALS INC , KROGER CO , THE & 13 AVKARE, INC : Conor Donze 14 LEWIS BRISBOIS BISGAARD & SMITH, LLP 550 E Swedesford Road, Suite 270 15 Wayne, Pennsylvania 19087 215-977-4093 conor.donze@lewisbrisbois.com</p> <p>16</p> <p>17 FOR AMERISOURCEBERGEN CORPORATION: Jeffrey D Geoppinger 19 ULMER & BERNE, LLP 312 Walnut Street, Suite 1400 20 Cincinnati, Ohio 45202 513-698-5038 jgeoppinger@ulmer.com</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 8</p> <p>1 APPEARANCES (Continued)</p> <p>2</p> <p>3 FOR ALBERTSONS COMPANIES LLC: Christopher B Henry 4 BUCHANAN INGERSOLL & ROONEY PC Carillon Tower 5 227 West Trade Street, Suite 600 Charlotte, North Carolina 28202 6 704-444-3475 christopher.henry@bipc.com</p> <p>7</p> <p>8 FOR MYLAN PHARMACEUTICALS INC , AND MYLAN 9 LABORATORIES, LTD : Frank H Stoy 10 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP One Oxford Centre 11 301 Grant Street, 38th Floor Pittsburgh, Pennsylvania 15219 12 412-263-4397 fhs@pietragallo.com</p> <p>13</p> <p>14 ALSO PRESENT: 15 Shane Ramirez, Videographer Jason Novak, Trial Tech 16 Tom Karwacki, Trial Tech</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 7</p> <p>1 APPEARANCES (Continued)</p> <p>2</p> <p>3 FOR PFIZER INC , VALEANT PHARMACEUTICALS 4 INTERNATIONAL, INC , BAUSCH & LOMB INCORPORATED, AND ATON PHARMA, INC : Liza M Walsh Christine I Gannon 6 WALSH PIZZI O'REILLY FALANGA, LLP Three Gateway Center 7 100 Mulberry Street, 15th Floor Newark, New Jersey 07102 8 973-757-1100 lwalsh@walsh.law cgannon@walsh.com</p> <p>9</p> <p>10 FOR CVS HEALTH CO : Kara Kapke 12 BARNES & THORNBURG, LLP 11 S Meridian Street 13 Indianapolis, Indiana 46204 317-231-6491 kara.kapke@btlaw.com</p> <p>14</p> <p>15 FOR H J HARKINS CO , INC : Geoffrey M Coan 17 HINSHAW & CULBERTSON, LLP 53 State Street, 27th Floor 18 Boston, Massachusetts 02109 617-213-7000 gcoan@hinshawlaw.com</p> <p>19</p> <p>20 FOR OPTUM, INC & OPTUMRX: Shevon D B Rockett 22 DORSEY & WHITNEY, LLP 51 West 52nd Street 23 New York, New York 10019 212-415-9357 rockett.shevon@dorsey.com</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 9</p> <p>1 INDEX</p> <p>2</p> <p>3 PAGE</p> <p>4 APPEARANCES 2</p> <p>5 JOHN L QUICK</p> <p>6 EXAMINATION</p> <p>7 By Ms Isidro 12</p> <p>8 By Mr Goldberg 244</p> <p>9 CORRECTION PAGE 274</p> <p>10 SIGNATURE PAGE 275</p> <p>11 REPORTER'S CERTIFICATION 276</p> <p>12</p> <p>13 EXHIBITS</p> <p>14 PAGE LINE</p> <p>15 Exhibit 1, 28 15</p> <p>16 Curriculum Vitae (No Bates - 6 pages)</p> <p>17 Exhibit 2, 34 21</p> <p>18 Consulting Agreement (No Bates - 4 pages)</p> <p>19 Exhibit 3, 37 4</p> <p>20 Quick & Associates Invoices (No Bates - 7 pages)</p> <p>21 Exhibit 4, 46 19</p> <p>22 Amended Notice of Videotaped Deposition (No Bates - 9 pages)</p> <p>23 Exhibit 5, 48 1</p> <p>24 Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion (No Bates - 27 pages)</p> <p>25 Exhibit 6, 48 21</p> <p>Expert Declaration of John L Quick (No Bates - 49 pages)</p> <p>24</p> <p>25</p>

<p style="text-align: right;">Page 10</p> <p>1 EXHIBITS (Continued)</p> <p>2 PAGE LINE</p> <p>3 Exhibit 7, 50 5 M7(R1) Assessment and Control of DNA</p> <p>4 Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit</p> <p>5 Potential Carcinogenic Risk (No Bates - 131 pages)</p> <p>6 Exhibit 8, 85 1 FDA Statement on FDA's ongoing</p> <p>7 investigation into valsartan impurities and recalls and an update</p> <p>8 on FDA's current findings</p> <p>9 (No Bates - 7 pages) Exhibit 9, 98 25</p> <p>10 Food and Drug Administration Compliance Program Guidance Manual</p> <p>11 (No Bates - 31 pages) Exhibit 10, 103 1</p> <p>12 Facts About the Current Good Manufacturing Practices (CGMPs)</p> <p>13 (No Bates - 3 pages) Exhibit 11, 136 18</p> <p>14 Chapter 5 FD&C Act Subchapter A Drugs and Devices Sec 501 [351]</p> <p>15 (No Bates - 5 pages) Exhibit 12, 141 11</p> <p>16 21 U.S. Code § 352 - Misbranded drugs and devices</p> <p>17 (No Bates - 14 pages) Exhibit 13, 148 14</p> <p>18 08/11/2000 Warning Letter (No Bates - 3 pages)</p> <p>19 Exhibit 14, 162 13 Inspection Observations</p> <p>20 (No Bates - 2 pages) Exhibit 15, 199 3</p> <p>21 Email chain originating 08/10/2018 from Jens Nassall, Subject "FDA-483</p> <p>22 observations from 2017 and current Valsartan situation"</p> <p>23 (ZHP00912962 - ZHP00912967) Exhibit 16, 217 14</p> <p>24 ZHP June 2015 Audit Report (TEVA-MDL2875-00399168 -</p> <p>25 TEVA-MDL2875-00399246)</p>	<p style="text-align: right;">Page 12</p> <p>1 THE VIDEOGRAPHER: Here begins the</p> <p>2 deposition of John Quick. Today's date is</p> <p>3 January 27th, 2022. The time is 9:33 a.m.</p> <p>4 Will the court reporter please swear</p> <p>5 in the witness?</p> <p>6 THE REPORTER: And will you introduce</p> <p>7 yourselves for the record?</p> <p>8 MS. ISIDRO: Nilda Isidro from</p> <p>9 Greenberg Traurig on behalf of defendant, Teva.</p> <p>10 MR. KERNER: I'm Glenn Kerner from</p> <p>11 Greenberg Traurig, also on behalf of Teva.</p> <p>12 MR. DAVIS: John Davis, Slack Davis</p> <p>13 Sanger, on behalf of the plaintiffs.</p> <p>14 MS. HILTON: Layne Hilton, Kanner &</p> <p>15 Whiteley on behalf of the plaintiffs.</p> <p>16 MS. WHITELEY: Conlee Whiteley,</p> <p>17 Kanner & Whiteley, on behalf of plaintiffs.</p> <p>18 JOHN L. QUICK,</p> <p>19 having been first duly sworn, testified as follows:</p> <p>20 EXAMINATION</p> <p>21 BY MS. ISIDRO:</p> <p>22 Q. Good morning, Mr. Quick.</p> <p>23 A. Good morning.</p> <p>24 Q. My name is Nilda Isidro. I am from the</p> <p>25 law firm of Greenberg Traurig and I represent</p>
<p style="text-align: right;">Page 11</p> <p>1 EXHIBITS (Continued)</p> <p>2 PAGE LINE</p> <p>3 Exhibit 17, 222 7 ZHP May 2018 Audit Report</p> <p>4 (TEVA-MDL2875-00118147 - TEVA-MDL2875-00118208)</p> <p>5 Exhibit 18, 225 4 Department of Health and Human</p> <p>6 Services Inspection Report (10 pages - No Bates)</p> <p>7 Exhibit 19, 245 4 Establishment Inspection Report</p> <p>8 (ZHP01427917 - ZHP01427974) Exhibit 20, 248 8</p> <p>9 11/04/2021 Closeout Letter (No Bates - 2 pages)</p> <p>10 Exhibit 21, 254 11 Quality Risk Management Q9</p> <p>11 (No Bates - 23 pages) Exhibit 22, 257 20</p> <p>12 Standard Management Procedure (ZHP00000417 - ZHP00000470)</p> <p>13 Exhibit 23, 261 8 Change Request Form</p> <p>14 (ZHP01843066 - ZHP01843119) Exhibit 24, 265 7</p> <p>15 Standard Management Procedure (ZHP00469139 - ZHP0469162)</p> <p>16 Exhibit 25, 270 10 Excerpts of Videotaped Deposition of</p> <p>17 Jucai Ge, April 29, 2021 (No Bates - 4 pages)</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 13</p> <p>1 defendant, Teva. We're meeting for the first time</p> <p>2 this morning. Correct?</p> <p>3 A. That's correct.</p> <p>4 Q. I'm going to be asking you some questions</p> <p>5 today. And if we could start, could you please</p> <p>6 state your full name for the record.</p> <p>7 A. John Lowell Quick.</p> <p>8 Q. What is your current professional</p> <p>9 address?</p> <p>10 A. W1800 County Road B, Genoa City,</p> <p>11 Wisconsin 53128.</p> <p>12 Q. Thank you. Mr. Quick, you've been</p> <p>13 deposed before. Correct?</p> <p>14 A. I have.</p> <p>15 Q. So you know how this goes, but I'm just</p> <p>16 going to go over a few ground rules before we get</p> <p>17 started.</p> <p>18 As you know, there is a court reporter to</p> <p>19 your left taking down everything that anyone in the</p> <p>20 room says. For that reason it's very important that</p> <p>21 you answer verbally. So, for example, saying "yes"</p> <p>22 or "no," rather than nodding your head or saying</p> <p>23 "uh-huh" or "uh-uh," just so that we can make sure</p> <p>24 that the written transcript is clear.</p> <p>25 It's also important that before you start</p>

<p style="text-align: right;">Page 14</p> <p>1 to answer a question, you wait for me to finish 2 getting the question out completely, not anticipate 3 what I'm trying to ask. And this is, again, just so 4 that the court reporter isn't trying to take both of 5 us down talking at the same time. 6 If at any time you don't understand my 7 question or you don't hear me, please let me know. 8 I'm happy to repeat it or to clarify whatever might 9 be confusing about the question. But if you do 10 answer my question, I'm going to assume that you 11 understood it. Fair enough? 12 A. Fair. 13 Q. All right. If you need a break at any 14 time, please let me know. I would just ask that if 15 there is a question pending, we get the question 16 answered first and then we can take a break. 17 Do you have any questions at all -- oh, 18 one more thing. In addition to the folks in the 19 room, we have some folks on Zoom. So, for example, 20 when we're dealing with exhibits, there may be a 21 little bit of a pause as we wait for the exhibit to 22 get up on the Zoom as well. And there may be folks 23 asking questions on the Zoom later on. All right? 24 Is there any reason, as you sit here 25 today, why you may not be able to give accurate and</p>	<p style="text-align: right;">Page 16</p> <p>1 have you ever been retained as an expert witness? 2 A. Yes. 3 Q. On how many occasions have you been 4 retained as an expert witness? 5 A. Multiple occasions. 6 Q. Can you approximate a number? 7 A. Approximately five. It could be more or 8 less. 9 Q. Fewer than ten? 10 A. Fewer than ten. 11 Q. Okay. And have you ever testified, prior 12 to today, at a deposition as an expert witness? 13 A. Yes. 14 Q. On how many occasions? 15 A. Probably the same number. 16 Q. So there haven't been any cases where you 17 were retained where you did not testify at 18 deposition? 19 A. I don't believe so. 20 Q. Okay. Have you ever testified at a 21 deposition other than as an expert witness? 22 A. Yes. 23 Q. On how many occasions? 24 A. 10, 15 times maybe. 25 Q. When was the last time that you testified</p>
<p style="text-align: right;">Page 15</p> <p>1 truthful testimony? 2 A. No. 3 Q. You're not on any medications that might 4 impact your ability to give accurate and truthful 5 testimony? 6 A. No, I'm not. 7 MS. ISIDRO: And, again, just 8 remember to let me finish my question before you 9 start to answer. 10 MR. DAVIS: And give me a little time 11 to place an objection, as appropriate, as well. So 12 build even more of a little delay in there. Thanks. 13 Q. And do you want to read and sign the 14 deposition? 15 A. I'm sorry? 16 MR. DAVIS: We can handle that at the 17 end, Nilda. 18 MS. ISIDRO: Okay. Sure. 19 Q. All right. Mr. Quick, have you ever been 20 a party to a lawsuit? 21 A. Maybe you can rephrase. I'm not sure. 22 Q. Sure. Have you ever been the plaintiff 23 or the defendant in a lawsuit? 24 A. No. 25 Q. Have you -- aside from this litigation,</p>	<p style="text-align: right;">Page 17</p> <p>1 at a deposition not as an expert witness? 2 A. I'm not certain, but maybe 15 years ago. 3 Q. And what was the -- what was the context 4 for your being deposed at that time? 5 A. Probably that -- I'm not certain the time 6 frames, but at that time it may have been related to 7 a situation at Baxter, my former employee, when they 8 asked me to testify on a situation that had occurred 9 when I was in an employ at the company. 10 Q. So for the 10 to 15 times that you 11 testified not as an expert witness, did those all 12 relate to your employment at Baxter? 13 A. No. 14 Q. Okay. About how many of them related to 15 your employment at Baxter? 16 A. Probably all of them, but maybe two or 17 three. 18 Q. And what did those two or three that were 19 not related to Baxter relate to? 20 A. We're going a long ways back. One 21 related to a situation with a contract manufacturer 22 in California. One related to a medical device 23 company. Those are the two I can recall. 24 Q. And so in the matter involving the 25 contract manufacturer in California, what was the</p>

<p style="text-align: right;">Page 18</p> <p>1 reason for you being deposed?</p> <p>2 A. The issue related to a -- one of their</p> <p>3 customers. It was a contract dispute and the issue</p> <p>4 related to whether they fulfilled their contract.</p> <p>5 And so I was brought in as an expert on Q7 relative</p> <p>6 to APIs.</p> <p>7 Q. Okay. So that was one of the instances</p> <p>8 where you were deposed as an expert witness?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. So focusing only on the times</p> <p>11 where you were deposed not as an expert witness, you</p> <p>12 said there were about 10 to 15 of those.</p> <p>13 Is that right?</p> <p>14 A. No.</p> <p>15 Q. Okay.</p> <p>16 A. I said there were probably three or four.</p> <p>17 Again, we're really stretching my memory. Some of</p> <p>18 these go back years.</p> <p>19 Q. Okay. I want to make sure I understood</p> <p>20 because what I had understood from your testimony</p> <p>21 was that you had been deposed approximately five</p> <p>22 times as an expert witness and then approximately 10</p> <p>23 to 15 times not as an expert witness.</p> <p>24 A. Okay. That's probably right.</p> <p>25 Q. So were you ever deposed as a fact</p>	<p style="text-align: right;">Page 20</p> <p>1 an expert witness.</p> <p>2 Q. And would that have been in connection</p> <p>3 with Baxter or something else?</p> <p>4 A. Something else.</p> <p>5 Q. And what was that?</p> <p>6 A. So the one I indicated was a medical</p> <p>7 device company. One was a contract manufacturer in</p> <p>8 California. There was another one that -- back in</p> <p>9 the 2012 time frame, where I was an expert witness</p> <p>10 for a private equity company. They were doing</p> <p>11 battle with another private equity company over an</p> <p>12 escrow. And so I was an expert witness. And that</p> <p>13 situation related to sterile aseptic processing.</p> <p>14 Q. Okay. And in those instances the company</p> <p>15 on whose behalf you were testifying was your</p> <p>16 employer?</p> <p>17 MR. DAVIS: Objection to the use of</p> <p>18 the word "employer."</p> <p>19 A. I wasn't an employer. I was a</p> <p>20 consultant. I was retained as a consultant.</p> <p>21 Q. Okay. But you were retained?</p> <p>22 A. Right.</p> <p>23 Q. When you're testifying as an expert or as</p> <p>24 a consultant, you're compensated. Correct?</p> <p>25 A. That's correct.</p>
<p style="text-align: right;">Page 19</p> <p>1 witness, so not as an expert, in connection with</p> <p>2 anything other than your employment at Baxter?</p> <p>3 A. I don't believe so. I would qualify that</p> <p>4 these were not characterized the way you're</p> <p>5 characterizing them, at the time.</p> <p>6 Q. Okay. How were they -- how were they</p> <p>7 characterized?</p> <p>8 A. I'm saying they were not characterized at</p> <p>9 all.</p> <p>10 Q. Am I understanding that you didn't</p> <p>11 necessarily know whether you were testifying as an</p> <p>12 expert witness or as a fact witness?</p> <p>13 A. Well, to differentiate --</p> <p>14 THE WITNESS: I'm sorry.</p> <p>15 MR. DAVIS: I'm going to object for</p> <p>16 the record. You can answer the question.</p> <p>17 A. The differentiation wasn't made at the</p> <p>18 time.</p> <p>19 Q. Okay. So let me ask it this way.</p> <p>20 When you're testifying as an expert</p> <p>21 witness, is it always the case that you are retained</p> <p>22 as an expert in that matter?</p> <p>23 A. Going back all those years, I honestly</p> <p>24 don't know how I was retained. In some cases I was</p> <p>25 actually working for the group where I was acting as</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. Have you ever provided deposition</p> <p>2 testimony for which you were not compensated?</p> <p>3 A. I've had -- I've been at -- well, for</p> <p>4 example, the Baxter deposition I referred to back</p> <p>5 10, 15 years ago, I was not compensated for that.</p> <p>6 It wasn't explained I was an expert witness. I was</p> <p>7 just called to testify. I was not compensated for</p> <p>8 that.</p> <p>9 Q. And what did that lawsuit involve, in</p> <p>10 general terms?</p> <p>11 A. It related to a labeling issue with a --</p> <p>12 one of the products that Baxter had. And it goes</p> <p>13 back to the early '90s.</p> <p>14 Q. And you were deposed when in connection</p> <p>15 with that case?</p> <p>16 A. Yes.</p> <p>17 Q. My question was you were deposed when in</p> <p>18 connection with that case?</p> <p>19 A. Oh. I'm saying it was probably about 15</p> <p>20 years ago. It was long after I left Baxter.</p> <p>21 Q. Okay. Have you ever testified at trial</p> <p>22 as an expert witness?</p> <p>23 A. Yes.</p> <p>24 Q. On how many occasions?</p> <p>25 A. Once.</p>

<p style="text-align: right;">Page 22</p> <p>1 Q. And what case was that?</p> <p>2 A. This was the case on the aseptic</p> <p>3 processing issues where the two private equity</p> <p>4 groups were disputing the escrow amount.</p> <p>5 Q. When did that trial take place?</p> <p>6 A. I believe it was somewhere in the 20 --</p> <p>7 2012 time frame. If we need an exact date, I can</p> <p>8 get an exact date.</p> <p>9 Q. What were -- what were the names of the</p> <p>10 parties in that lawsuit?</p> <p>11 A. I don't recall offhand, but I can</p> <p>12 certainly get that if we need that.</p> <p>13 Q. Okay.</p> <p>14 A. It's been a long time. It's been ten</p> <p>15 years.</p> <p>16 Q. Do you remember the name of the private</p> <p>17 equity firm?</p> <p>18 A. I don't offhand.</p> <p>19 Q. Okay. To your knowledge, have you ever</p> <p>20 had your opinions excluded or limited by any court?</p> <p>21 A. Not that I'm aware of.</p> <p>22 Q. So we talked about at least two instances</p> <p>23 where you were retained as a consultant. That's the</p> <p>24 contract manufacturer issue in California and the</p> <p>25 medical device company issue. Correct?</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. And prior to that, when was the last time</p> <p>2 that you testified as an expert witness?</p> <p>3 A. Probably the situation I referred to back</p> <p>4 in 2012.</p> <p>5 Q. Okay. That was the contract manufacturer</p> <p>6 issue?</p> <p>7 A. This was the two private equity groups.</p> <p>8 Q. Two private equity groups.</p> <p>9 A. Again, these were -- I'm trying to recall</p> <p>10 from memory for long periods of time in the past.</p> <p>11 MR. DAVIS: And I just caution you</p> <p>12 not to speculate. If you don't remember something,</p> <p>13 you don't remember it, but...</p> <p>14 Q. So prior to the case with the two private</p> <p>15 equity groups, when was the last time before that</p> <p>16 that you testified as an expert witness?</p> <p>17 A. The two cases that I referenced, one was</p> <p>18 the medical device company and one was the contract</p> <p>19 manufacturer. I'm not sure which was first, which</p> <p>20 was last.</p> <p>21 Q. And the case with the contract</p> <p>22 manufacturer in California that one was</p> <p>23 approximately when?</p> <p>24 A. It was approximately 15 years ago.</p> <p>25 Q. And how about the one with the medical</p>
<p style="text-align: right;">Page 23</p> <p>1 A. That's correct. Just to clarify, though,</p> <p>2 I've obviously been retained as a consultant for</p> <p>3 many other situations where I was not testifying as</p> <p>4 an expert witness.</p> <p>5 Q. Okay. So these are the two that you</p> <p>6 recall --</p> <p>7 A. Right.</p> <p>8 Q. -- where you did testify where you were</p> <p>9 being retained as a consultant but you also</p> <p>10 testified as an expert witness. Correct?</p> <p>11 A. Correct.</p> <p>12 Q. And you also mentioned there were about</p> <p>13 five instances where you have been retained as an</p> <p>14 expert and testified as an expert at a deposition.</p> <p>15 Correct?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. What was the last time, the most</p> <p>18 recent time, that you testified as a retained expert</p> <p>19 witness at a deposition?</p> <p>20 A. Two -- almost exactly two years ago.</p> <p>21 Q. What was that case?</p> <p>22 A. This was the hernia mesh case.</p> <p>23 Q. Were you testifying on behalf of the</p> <p>24 plaintiff in that case?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 25</p> <p>1 device company?</p> <p>2 A. It was somewhere in the same time frame.</p> <p>3 Q. Do you recall providing testimony as an</p> <p>4 expert witness at any time prior to that?</p> <p>5 A. I don't believe so, but I'm not certain.</p> <p>6 Q. In the matter involving the two private</p> <p>7 equity groups, were you testifying on behalf of the</p> <p>8 plaintiff or the defendant?</p> <p>9 A. That's a good question. I'm not sure</p> <p>10 which was which.</p> <p>11 Q. And in the matter involving the contract</p> <p>12 manufacturer in California, were you testifying on</p> <p>13 behalf of the plaintiff or the defendant?</p> <p>14 A. Probably the defendant in that case.</p> <p>15 MR. DAVIS: I'd caution you not to</p> <p>16 speculate. If you know, you know --</p> <p>17 A. I'm --</p> <p>18 MR. DAVIS: -- if you don't, you</p> <p>19 don't.</p> <p>20 A. -- I'm not certain who was suing who</p> <p>21 there, but...</p> <p>22 Q. Okay. And in the matter involving the</p> <p>23 medical device company, were you testifying on</p> <p>24 behalf of the plaintiff or the defendant?</p> <p>25 A. Again, I'm -- I'm not certain.</p>

7 (Pages 22 - 25)

<p style="text-align: right;">Page 26</p> <p>1 Q. Are you listed in any databases of 2 experts? 3 A. I'm sorry? 4 Q. Are you listed in any databases of 5 experts? 6 A. Not that I'm aware of. 7 Q. Have you ever advertised for your 8 services as an expert? 9 A. No. 10 Q. Have you ever spoken or given a 11 presentation to a group of lawyers? 12 MR. DAVIS: Objection; vague. 13 But you can answer. 14 A. Maybe you want to clarify that a little. 15 Q. What do you need clarification on? 16 A. Well, I don't know. You said a group of 17 lawyers. I mean, I -- I deal with lawyers all the 18 time. 19 Q. So other than in a matter where you've 20 been engaged as an expert, have you ever given a 21 presentation to a group of lawyers? 22 MR. DAVIS: Same objection. 23 You can answer. 24 A. Like I said, I deal with lawyers all the 25 time and so when you say "a presentation to a group</p>	<p style="text-align: right;">Page 28</p> <p>1 have you ever given a presentation to a group of 2 lawyers? 3 A. Not that I'm aware of. 4 Q. Have you ever spoken at a legal 5 conference? 6 A. I did speak years ago at -- actually, I 7 think it's in my CV. I forget the group. We could 8 pull up my CV and we could look. So there was a 9 presentation years ago. I think it was -- I want to 10 believe a group sponsored it. But this has been a 11 long time ago. 12 Q. All right. 13 MS. ISIDRO: Why don't we go ahead 14 and mark that CV as Exhibit 1. 15 (Exhibit 1 was marked.) 16 MR. DAVIS: Are you going to have a 17 copy for me, Nilda? 18 MS. ISIDRO: Yes, I am. Just bear 19 with me as I'm actually marking the exhibit. 20 MR. DAVIS: Thank you. 21 Q. Mr. Quick, I've just handed you 22 Exhibit 1. Is that your CV? 23 A. Yes. 24 Q. You said you would be able to locate that 25 presentation on your CV. So if you could take a</p>
<p style="text-align: right;">Page 27</p> <p>1 of lawyers," it's not very clear what you're trying 2 to ask. 3 Q. So -- so is that a "yes" -- 4 A. I don't know. 5 Q. -- you have given a presentation to a 6 group of lawyers? I mean, you said you deal with 7 lawyers all the time. 8 A. So I -- so when you're saying a 9 presentation, so I deal with lawyers all the time. 10 And so when you're asking about giving a 11 presentation, I mean, I've had interactions with 12 groups of lawyers. I'm -- I'm not really sure where 13 you're going with this, so I'm not sure how to 14 answer your question. 15 Q. In what context do you deal with lawyers 16 all the time? 17 A. So I -- I, again -- I'm involved very 18 heavily in diligence for groups that want to buy 19 another company and lawyers are involved in all of 20 these situations. 21 Q. And are you -- in those instances, have 22 you been hired as a consultant to provide diligence? 23 A. Yes. 24 Q. So other than in a situation where you've 25 been hired as a consultant or hired as an expert,</p>	<p style="text-align: right;">Page 29</p> <p>1 I look and do that for me, please. 2 A. (Pause.) 3 It's the last one on Page 6. This was 4 the FDLI. 5 Q. I see. July 11, 1995? 6 A. That's correct. 7 Q. Okay. That's the only time you've ever 8 spoken at a legal conference? 9 A. I -- I believe that to be the case. 10 Q. Are you affiliated with any expert 11 witness services? 12 A. No. 13 (Discussion off the written record.) 14 MS. ISIDRO: Why don't we go off the 15 record for a minute and take care of the issue. 16 THE VIDEOGRAPHER: Off the record at 17 9:56 a.m. 18 (Break.) 19 THE VIDEOGRAPHER: Back on the record 20 10:02 at a.m. 21 Q. Mr. Quick, have you ever done consulting 22 work for a pharmaceutical company? 23 A. Yes. 24 Q. How many times? 25 A. I don't have a number.</p>

<p style="text-align: right;">Page 30</p> <p>1 Q. More than ten?</p> <p>2 A. More than ten.</p> <p>3 Q. More than 20?</p> <p>4 A. Probably. I -- I really don't know.</p> <p>5 Q. In what context have you provided</p> <p>6 consulting to pharmaceutical companies?</p> <p>7 A. Primarily as it relates to quality and</p> <p>8 regulatory and/or diligence.</p> <p>9 Q. Have you ever provided consulting</p> <p>10 services to any of the defendants in this</p> <p>11 litigation?</p> <p>12 A. Yes.</p> <p>13 Q. Which ones?</p> <p>14 A. Mylan.</p> <p>15 Q. When was that?</p> <p>16 A. I put the dates -- I think the dates are</p> <p>17 in the -- in the report. If I had the report, I</p> <p>18 could give you the exact dates.</p> <p>19 Q. Other than Mylan, have you ever provided</p> <p>20 consulting services for any defendant in this</p> <p>21 litigation?</p> <p>22 A. No.</p> <p>23 Q. And you've never provided consulting</p> <p>24 services for Teva. Correct?</p> <p>25 A. No, I've not, although I've been to Teva</p>	<p style="text-align: right;">Page 32</p> <p>1 Associates is spent on consulting in connection with</p> <p>2 legal matters, lawsuits?</p> <p>3 A. Legal matters?</p> <p>4 Q. Uh-huh.</p> <p>5 A. Would you want to define what you mean</p> <p>6 when you say "legal matters"?</p> <p>7 Q. I said "lawsuits."</p> <p>8 A. A low percentage.</p> <p>9 Q. 25 percent?</p> <p>10 A. Probably less than that.</p> <p>11 Q. 10 percent?</p> <p>12 A. Probably less than that. I don't have a</p> <p>13 number.</p> <p>14 Q. Are you currently consulting in</p> <p>15 connection with any litigation, other than this one?</p> <p>16 A. Not that I'm aware of.</p> <p>17 Q. You would be aware of matters that you</p> <p>18 are currently consulting on. Correct?</p> <p>19 A. I am aware. I do a lot of consulting for</p> <p>20 a lot of different entities. There's -- there's no</p> <p>21 specific litigation that I'm aware of for any of</p> <p>22 those.</p> <p>23 Q. How much money did you make last year</p> <p>24 from serving as an expert witness?</p> <p>25 A. I don't have that number.</p>
<p style="text-align: right;">Page 31</p> <p>1 facilities as part of another situation.</p> <p>2 Q. And what situation was that?</p> <p>3 A. Diligence.</p> <p>4 Q. So you were providing diligence for</p> <p>5 another entity regarding Teva?</p> <p>6 A. That's correct.</p> <p>7 Q. And that's disclosed in your report as</p> <p>8 well. Correct?</p> <p>9 A. Correct.</p> <p>10 Q. What percentage of your income is</p> <p>11 generated through legal consulting?</p> <p>12 A. Would you repeat that, please?</p> <p>13 Q. What percentage of your income is</p> <p>14 generated through legal consulting?</p> <p>15 MR. DAVIS: I'm going to -- before he</p> <p>16 answers that, I'm going to object to that as vague.</p> <p>17 A. It's a -- it's a very complicated</p> <p>18 situation. All my consulting is done through</p> <p>19 Quick & Associates. I receive no salary as a result</p> <p>20 of working for Quick & Associates. I have a pension</p> <p>21 from Baxter International, which is where my income</p> <p>22 is. There's -- it's -- if we want to spend the</p> <p>23 time, I could get into the specifics as to how our</p> <p>24 finances are handled.</p> <p>25 Q. What percentage of your time at Quick &</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. How much money have you made so far this</p> <p>2 year from serving as an expert witness?</p> <p>3 A. I've received nothing this year as a</p> <p>4 result of serving as an expert witness.</p> <p>5 Q. Have you billed for any services rendered</p> <p>6 as an expert witness over the course of this year so</p> <p>7 far?</p> <p>8 A. In 2020? No.</p> <p>9 Q. In 2022?</p> <p>10 A. 2022, no.</p> <p>11 Q. In 2021, did you provide any consulting</p> <p>12 or expert witness services in connection with any</p> <p>13 litigation, other than this one?</p> <p>14 A. I don't believe so.</p> <p>15 Q. How much are you charging per hour for</p> <p>16 your work in this case?</p> <p>17 A. \$400 per hour for consulting, \$500 for</p> <p>18 depositions, and any trial work.</p> <p>19 Q. And is that \$500 flat per hour for</p> <p>20 depositions?</p> <p>21 A. What do you mean, "flat"?</p> <p>22 Q. 500, not 540 or --</p> <p>23 A. \$500, yes.</p> <p>24 Q. \$500.</p> <p>25 A. I believe that's in the report as well.</p>

<p style="text-align: right;">Page 34</p> <p>1 Q. How do you track the time that you spend 2 on this litigation? 3 A. How do I track? 4 Q. Uh-huh. 5 A. I track all of my time. I've got a 6 internal spreadsheet system that I use, so I -- 7 that's how I track it. 8 Q. So you have records of all of the time 9 that you have spent on this matter. Correct? 10 A. I do. 11 Q. And that includes your time spent during 12 calendar year 2022? 13 A. Yes. 14 Q. How often do you generate invoices in 15 connection with your work on this litigation? 16 A. There is no predetermined frequency. 17 Q. So how do you determine at any given 18 point when to issue an invoice? 19 A. It's usually after some significant work 20 has occurred. There is no set time frame. 21 (Exhibit 2 was marked.) 22 Q. All right. And we've marked as Exhibit 2 23 a document that has "Consulting Agreement" as the 24 title. I'm handing it to you right now. Please 25 take a look at that.</p>	<p style="text-align: right;">Page 36</p> <p>1 at \$525 per hour. 2 A. I see that. 3 Q. Is that correct? 4 A. That is correct, and what I said earlier 5 was incorrect. 6 Q. Okay. So your hourly rate for testimony, 7 including here today, is 525 an hour? 8 A. That's correct. 9 Q. And it also says that there is an 10 alternative fee of 4,200 -- \$4,200 per day, 11 regardless of the number of hours in the day 12 exceeding eight hours? 13 A. That's correct. 14 Q. Does that apply for purposes of your 15 deposition at your deposition here today? 16 A. Yes. 17 MR. DAVIS: Assuming we exceed eight 18 hours. 19 Q. But there is no reason that that 20 provision would not apply with respect to a day of 21 deposition testimony, including today, if we exceed 22 eight hours? 23 A. That's correct. 24 Q. I'm going to mark some invoices as the 25 next few exhibits. Just bear with us a moment. You</p>
<p style="text-align: right;">Page 35</p> <p>1 A. (Pause.) 2 Q. Is that your consulting agreement in 3 connection with this litigation? 4 A. It is. 5 Q. And if you turn to the second page, there 6 is a heading for "Compensation." Correct? 7 A. Correct. 8 Q. And that first section, 3.1, states that: 9 Compensation will be at the rate of \$400 per hour 10 for consulting work. 11 That's -- you mentioned previously. 12 Correct? 13 A. Correct. 14 Q. And it also says: There is an 15 alternative fee of \$3,200 per day, regardless of the 16 number of hours in the day exceeding eight hours? 17 A. Correct. 18 Q. Have there been any instances in this 19 litigation where you have used that 3,200 per day in 20 a given day? 21 A. I don't believe so, but, I -- I'd have to 22 go back and check. 23 Q. And continuing in that section, it says 24 that: For expert testimony work, i.e., trial 25 testimony or deposition testimony, the rate will be</p>	<p style="text-align: right;">Page 37</p> <p>1 know what, I'm going to do this as a composite 2 exhibit so we just mark a single exhibit. Just bear 3 with me. 4 (Exhibit 3 was marked.) 5 MR. DAVIS: Are you going to order 6 them in chronological order, Nilda? 7 MS. ISIDRO: Sure, we can do that. 8 Q. Okay. So I'm handing you what's been 9 marked as Exhibit 3. Can you confirm for me that it 10 contains seven pages of invoices? 11 A. (Pause.) 12 Yes. 13 Q. Great. 14 And the first invoice that's there is an 15 invoice from July 2nd, 2020. Correct? 16 A. Correct. 17 Q. That's Invoice QA973? 18 A. Correct. 19 Q. And that invoice is for a total of 20 \$12,400. Correct? 21 A. Correct. 22 Q. And have you been paid on that invoice? 23 A. Yes. 24 Q. The full amount? 25 A. Yes.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. Okay. And the next invoice is</p> <p>2 Invoice QA974 dated July 11th, 2020.</p> <p>3 A. (Pause.)</p> <p>4 Q. Is that right?</p> <p>5 A. That's right.</p> <p>6 Q. And that invoice is for a total of</p> <p>7 \$11,200. Correct?</p> <p>8 A. That's correct.</p> <p>9 Q. Were you paid on that invoice?</p> <p>10 A. I was.</p> <p>11 Q. The full amount?</p> <p>12 A. The full amount.</p> <p>13 Q. Okay. The next invoice is Invoice QA983.</p> <p>14 Is that right?</p> <p>15 A. That's correct.</p> <p>16 Q. Dated October 4th, 2020?</p> <p>17 A. That's correct.</p> <p>18 Q. For a total amount of \$19,600?</p> <p>19 A. That's correct.</p> <p>20 Q. Were you paid on that invoice?</p> <p>21 A. I was.</p> <p>22 Q. The full amount?</p> <p>23 A. The full amount.</p> <p>24 Q. The next invoice is Invoice No. QA990.</p> <p>25 Is that right?</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. Were you paid on that invoice?</p> <p>2 A. I was.</p> <p>3 Q. And were you paid the full amount?</p> <p>4 A. I was.</p> <p>5 Q. And the last invoice in Exhibit 3 is</p> <p>6 Invoice QA1034, dated November 7th, 2021. Is that</p> <p>7 right?</p> <p>8 A. That's right.</p> <p>9 Q. And that's for \$44,000. Correct?</p> <p>10 A. Correct.</p> <p>11 Q. Were you paid on that invoice?</p> <p>12 A. I was.</p> <p>13 Q. Were you paid the full amount?</p> <p>14 A. I was.</p> <p>15 Q. Have you issued any invoices since that</p> <p>16 November 7th, 2021, invoice?</p> <p>17 A. I don't believe so.</p> <p>18 Q. And have you issued any invoices, other</p> <p>19 than the seven invoices that we have here in</p> <p>20 Exhibit 3?</p> <p>21 A. Not that I'm aware of.</p> <p>22 Q. These invoices are addressed to</p> <p>23 Plaintiffs' Steering Committee. Correct?</p> <p>24 A. That's correct.</p> <p>25 Q. Who do you actually send your invoices to</p>
<p style="text-align: right;">Page 39</p> <p>1 A. Yes.</p> <p>2 Q. Dated December 5th, 2020. Correct?</p> <p>3 A. Yes.</p> <p>4 Q. For a total amount of \$15,600?</p> <p>5 A. Yes.</p> <p>6 Q. Were you paid on that invoice?</p> <p>7 A. I was.</p> <p>8 Q. Were you paid the full amount?</p> <p>9 A. Yes.</p> <p>10 Q. The next one is Invoice QA1003. Is that</p> <p>11 right?</p> <p>12 A. That's correct.</p> <p>13 Q. Dated May 2nd, 2021?</p> <p>14 A. Yes.</p> <p>15 Q. For a total amount of \$16,400?</p> <p>16 A. Yes.</p> <p>17 Q. Were you paid on that invoice?</p> <p>18 A. I was.</p> <p>19 Q. Were you paid the full amount?</p> <p>20 A. I was.</p> <p>21 Q. The next one is Invoice QA1016, dated</p> <p>22 July 18, 2021. Is that right?</p> <p>23 A. That's correct.</p> <p>24 Q. For a total amount of \$4,400?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 41</p> <p>1 when you generate them?</p> <p>2 A. I send these to Rosemarie Bogdan.</p> <p>3 Q. And that's true for all of the invoices?</p> <p>4 A. That's -- yes.</p> <p>5 Q. Okay. Following this November 7th, 2021,</p> <p>6 invoice, have you spent time on this litigation?</p> <p>7 A. Yes.</p> <p>8 Q. How much time?</p> <p>9 A. I don't know. I'd have to go back and</p> <p>10 check my records. I really don't know. If we -- if</p> <p>11 that's important, we could get that number.</p> <p>12 Q. Okay. And after today, do you intend to</p> <p>13 continue spending time on this litigation?</p> <p>14 MR. DAVIS: Objection; calls for</p> <p>15 speculation, I suppose.</p> <p>16 A. It's -- it's -- I don't know, unless --</p> <p>17 if I'm asked to, I probably would do so.</p> <p>18 Q. Is it --</p> <p>19 A. I haven't been asked, but I've -- if I</p> <p>20 was, I probably would do so.</p> <p>21 Q. Is it your understanding -- is it your</p> <p>22 understanding that your services will be ongoing</p> <p>23 during the pendency of the litigation?</p> <p>24 MR. DAVIS: Objection.</p> <p>25 You can answer.</p>

<p style="text-align: right;">Page 42</p> <p>1 A. We've had no concrete discussion that's 2 going to happen. I'm assuming it probably would, 3 but...</p> <p>4 Q. And so looking at these invoices, these 5 seven invoices that are in Exhibit 3, through 6 November 7th of 2021, you've been paid \$123,600 for 7 your work in connection with this litigation?</p> <p>8 A. I haven't added them up, but if that's 9 the number when they add up, that would be correct.</p> <p>10 Q. Who first contacted you in connection 11 with this litigation?</p> <p>12 A. Rosemarie.</p> <p>13 Q. And did you know Rosemarie before she 14 contacted you in connection with this litigation?</p> <p>15 A. No, I did not.</p> <p>16 Q. Did you have a relationship with any of 17 the plaintiffs' counsel or their firms prior to 18 this -- prior to being engaged to work on this 19 litigation?</p> <p>20 A. No.</p> <p>21 THE WITNESS: I'm sorry.</p> <p>22 MR. DAVIS: Just give me a little 23 time to place an objection.</p> <p>24 THE WITNESS: Okay.</p> <p>25 MR. DAVIS: So I'm going to object to</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Were you provided with everything you 2 asked for?</p> <p>3 A. I don't believe so. I don't believe all 4 the documents have yet been provided, but I don't -- 5 I'm not certain. I think most probably have, but 6 I'm not certain.</p> <p>7 Q. What did you request that was not 8 provided?</p> <p>9 A. I don't know. It was a two-page list and 10 I have not checked off which ones were not provided. 11 I could probably made that determination if we need 12 that information.</p> <p>13 Q. You still have a copy of that list?</p> <p>14 A. I do.</p> <p>15 Q. I'm going to ask you to make sure you 16 preserve a copy of that list.</p> <p>17 A. I will.</p> <p>18 Q. In connection with your work on this 19 litigation, is there anyone who assists you with 20 research?</p> <p>21 A. No.</p> <p>22 Q. Have you reviewed the opinions of any of 23 plaintiffs' other experts in connection with this 24 litigation?</p> <p>25 A. No, I have not.</p>
<p style="text-align: right;">Page 43</p> <p>1 that as vague.</p> <p>2 Q. When were you first contacted in 3 connection with this litigation?</p> <p>4 A. I don't have a date.</p> <p>5 Q. It would have been before July 2nd of 6 2020. Correct?</p> <p>7 A. That's correct.</p> <p>8 Q. And, in fact, it would have been before 9 May 28th of 2020, which is the first date reflected 10 on that July 2nd, 2020, invoice. Correct?</p> <p>11 A. That would be correct.</p> <p>12 Q. What were you asked to do when you were 13 contacted about this litigation?</p> <p>14 MR. DAVIS: I'm going to object. 15 But you can answer for now. 16 And I think the assignment he was 17 given is reflected in his declaration, but feel free 18 to answer.</p> <p>19 A. I was asked to -- again, we're going back 20 probably two years. I was asked to do consulting 21 work in regard to this litigation. I was asked what 22 documents I might need to review in the scope of 23 this, understanding where we were at that time. I 24 provided a list of documents to Rosemarie that I 25 thought I would need in order to do a review.</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Have you reviewed the opinions of any 2 defendants' experts in connection with this 3 litigation?</p> <p>4 A. No, I have not.</p> <p>5 Q. Were you provided with any assumptions 6 that you were asked to take as true in connection 7 with forming your litigations -- with forming -- let 8 me repeat that question from the beginning. 9 Were you provided with any assumptions 10 that you were asked to take as true in forming your 11 opinions in connection with this litigation?</p> <p>12 MR. DAVIS: Object to the form. 13 You can answer.</p> <p>14 A. I'm not sure I understand exactly what 15 you're asking. Maybe you want to clarify?</p> <p>16 Q. In forming your opinions in connection 17 with this litigation, were there any facts that you 18 assumed to be true and did not independently verify?</p> <p>19 A. No, not that I'm aware of.</p> <p>20 MR. DAVIS: And same objection to 21 form on that question.</p> <p>22 Q. Have you ever communicated with any of 23 the plaintiffs in this litigation?</p> <p>24 A. No.</p> <p>25 Q. Have you ever communicated with any of</p>

<p style="text-align: right;">Page 46</p> <p>1 their medical providers?</p> <p>2 A. No, I have not.</p> <p>3 Q. In connection with this litigation have</p> <p>4 you communicated with anyone at any of the defendant</p> <p>5 companies?</p> <p>6 A. No, I have not.</p> <p>7 Q. Have you ever reviewed any of plaintiffs'</p> <p>8 medical records?</p> <p>9 A. No, I have not.</p> <p>10 MR. DAVIS: We've been going about an</p> <p>11 hour. Do you want to take a break or...</p> <p>12 MS. ISIDRO: Sure. We can take a</p> <p>13 quick break.</p> <p>14 THE VIDEOGRAPHER: Off the record,</p> <p>15 10:28 a.m.</p> <p>16 (Break.)</p> <p>17 THE VIDEOGRAPHER: Back on the</p> <p>18 record. The time is 10:43 a.m.</p> <p>19 (Exhibit 4 was marked.)</p> <p>20 Q. Mr. Quick, I am handing you Exhibit 4,</p> <p>21 which is the notice of deposition -- the amended</p> <p>22 notice of deposition for your deposition today.</p> <p>23 Have you seen this before?</p> <p>24 A. I have.</p> <p>25 Q. And have you seen -- if you turn to</p>	<p style="text-align: right;">Page 48</p> <p>1 (Exhibit 5 was marked.)</p> <p>2 Q. Are you aware that this is one of the</p> <p>3 documents that was produced in response to the</p> <p>4 requests in your amended notice of deposition?</p> <p>5 A. There are a lot of documents. I'm not</p> <p>6 certain about this particular one.</p> <p>7 Q. Okay. Is this a document that you</p> <p>8 reviewed and relied on in forming your opinions in</p> <p>9 this litigation?</p> <p>10 A. If I referenced it in my report or listed</p> <p>11 in the report, I did. If not, it was not. I'd have</p> <p>12 to go back and look to verify for certain.</p> <p>13 Q. Okay.</p> <p>14 MR. DAVIS: And I'll object to</p> <p>15 compound on that.</p> <p>16 Q. All right. Why don't we go ahead and</p> <p>17 mark your report as the next exhibit, Exhibit No. 6.</p> <p>18 And, Mr. Quick, I've just handed you</p> <p>19 Exhibit No. 6. Is this a copy of your report in</p> <p>20 this litigation?</p> <p>21 (Exhibit 6 was marked.)</p> <p>22 A. It is.</p> <p>23 Q. And behind the report itself, there is an</p> <p>24 Exhibit A, is that right, following Page 37 of the</p> <p>25 report?</p>
<p style="text-align: right;">Page 47</p> <p>1 Page 6, there is a list of requests. Have you seen</p> <p>2 that before today?</p> <p>3 A. I have.</p> <p>4 Q. And did you assist in putting together</p> <p>5 documents responsive to those requests?</p> <p>6 A. Yes. I was provided a copy of this. I</p> <p>7 believe that you have been provided with responses</p> <p>8 to these.</p> <p>9 Q. So you're aware that we received some</p> <p>10 documents in response to these requests, and some</p> <p>11 written responses in response to these requests a</p> <p>12 couple of days ago?</p> <p>13 A. I am.</p> <p>14 Q. Did you assist in putting those together?</p> <p>15 MR. DAVIS: I'll object to the form</p> <p>16 on that.</p> <p>17 You can answer.</p> <p>18 A. I believe they provided documents to you</p> <p>19 that were already available. I didn't do any -- I</p> <p>20 don't believe I did any special work on this as a</p> <p>21 result of this. They were already there.</p> <p>22 Q. I am marking as Exhibit 5 a document</p> <p>23 that's titled: Guidance for Industry Presenting</p> <p>24 Risk Information in Prescription Drug and Medical</p> <p>25 Device Promotion.</p>	<p style="text-align: right;">Page 49</p> <p>1 A. There is.</p> <p>2 Q. Is that -- and the title of that</p> <p>3 Exhibit A is: Materials Relied Upon for the</p> <p>4 Declaration?</p> <p>5 A. That's correct.</p> <p>6 Q. Is that what you were referencing just a</p> <p>7 few minutes ago when you said that if -- if</p> <p>8 Exhibit 5 was listed in your report, then it was</p> <p>9 something that you relied on?</p> <p>10 A. That's correct.</p> <p>11 Q. And do you see Exhibit 5 listed within</p> <p>12 Exhibit A of your report?</p> <p>13 A. I don't see it, unless it was one of the</p> <p>14 links on the websites.</p> <p>15 Q. Looking at the links, is it -- is</p> <p>16 Exhibit 5 among any of those?</p> <p>17 A. I don't believe it is.</p> <p>18 Q. Okay. So Exhibit 5 is not something that</p> <p>19 you relied on in forming your opinions in connection</p> <p>20 with this litigation?</p> <p>21 A. Well, the documents I relied on, or the</p> <p>22 ones that are on the list, are the ones I footnoted.</p> <p>23 Q. Right. And Exhibit 5 is not --</p> <p>24 A. It doesn't appear to be.</p> <p>25 Q. All right. And we are marking as</p>

<p style="text-align: right;">Page 50</p> <p>1 Exhibit 7 a document that is titled: M7(R1) 2 Assessment and Control of DNA Reactive (Mutagenetic) 3 Impurities in Pharmaceuticals to Limit Potential 4 Carcinogenic Risk. 5 (Exhibit 7 was marked.) 6 Q. Mr. Quick, are you aware that this is one 7 of the documents that was produced to us as 8 responsive to the requests that were attached to 9 your amended notice of deposition? 10 A. Are you asking if it's on my list? 11 Q. No. I'm asking if you're aware that it 12 was one of the documents that was produced to us as 13 responsive to the requests that were attached to 14 your amended notice of deposition? 15 A. I'm not certain. 16 Q. So you do not know, one way or the other, 17 whether it was included? 18 MR. DAVIS: I think whether it is 19 included is just a fact. He can answer to whether 20 he's aware of it. 21 MS. ISIDRO: I'm asking as to what he 22 was aware of. 23 MR. DAVIS: Okay. Sure. Yeah. 24 MS. ISIDRO: Right. 25 A. I don't believe so.</p>	<p style="text-align: right;">Page 52</p> <p>1 A. I'm not sure I understand what you're 2 asking. 3 Q. Have there been any updates that should 4 be reflected on your CV that are not listed there? 5 Anything more recent, for example? 6 A. No. 7 Q. So the CV is complete and accurate as 8 reflected in Exhibit 1? 9 MR. DAVIS: Object to form. 10 You can answer. 11 A. That's correct. 12 Q. Okay. Turning back to the list of 13 documents that you relied on, Exhibit A to your 14 report? 15 MR. DAVIS: For the record, that's 16 Exhibit 6. 17 MS. ISIDRO: Correct. Exhibit A 18 within Exhibit 6 to this deposition. 19 Q. Are there any new materials that you have 20 reviewed in connection with this litigation since 21 putting together the list that's in front of you in 22 Exhibit A to Exhibit 6? 23 MR. DAVIS: Object to form. 24 You can answer. 25 A. I don't believe so.</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. You don't know one way or the other or 2 you -- 3 A. No, I -- if it's -- 4 MR. DAVIS: I caution you not to 5 speculate. 6 THE WITNESS: Okay. 7 A. So I don't know. 8 Q. Okay. And is Exhibit 7 one of the 9 documents that you reviewed and relied on in forming 10 your opinions in this litigation? 11 A. No. 12 MR. DAVIS: Same objection, compound. 13 Q. Is Exhibit 7 one of the documents that 14 you relied on in forming your opinions in this 15 litigation? 16 A. No. 17 Q. And I'll take back Exhibits 5 and 7. 18 A. Which -- which one you want? 19 Q. 5 and 7. Thank you. 20 And I'm going to hand you Exhibit 1 21 again, your CV. If you can just take a quick look 22 at that and let me know if there are any updates to 23 your CV that are not reflected on Exhibit 1? 24 MR. DAVIS: I'll object to that as 25 vague.</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. So, as you sit here today, you don't have 2 any updates to that list? 3 A. Not that I'm aware of. 4 Q. What did you do to prepare for this 5 deposition? 6 A. Well, I reread my report. We had 7 discussion yesterday afternoon and we had a call -- 8 MR. DAVIS: And I'll caution you not 9 to reveal the substance of those discussions. 10 THE WITNESS: Okay. 11 A. And there was a teleconference. 12 Q. And when you say "we" had a discussion, 13 who are you referring to? 14 A. The attorneys in this room. 15 Q. And that does not include myself. 16 Correct? 17 A. No, it did not include you. That's 18 correct. 19 Q. It also doesn't include my colleague, 20 Glenn Kerner. Correct? 21 A. That's correct. 22 Q. And when you reference a teleconference, 23 can you please tell me who was on that 24 teleconference? Who participated? 25 A. The three attorneys on the right side of</p>

<p style="text-align: right;">Page 54</p> <p>1 the room and some other folks. I don't recall who 2 else was on the call. We could get that list, but I 3 don't recall. 4 Q. Do you know whether everyone who was on 5 that call was an attorney for the plaintiffs in this 6 litigation? 7 A. I believe that to be the case. 8 Q. To the best of your knowledge, there was 9 no one on that call who was not an attorney for the 10 plaintiffs in this litigation? 11 A. That's correct. 12 Q. Other than yourself. Right? 13 A. Right. 14 Q. Okay. Turning back to your CV, 15 Exhibit 1. You've been an independent consultant 16 from 2003 to the present? 17 A. That's correct. 18 Q. And has that been exclusively through 19 your own company? 20 A. I'll clarify. There were one or two 21 situations where I was engaged by another consulting 22 firm to work with them, but it was still through my 23 own consulting firm. 24 Q. And your own consulting firm is Quick & 25 Associates?</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Okay. So, aside from the equestrian 2 businesses that are within Quick & Associates, does 3 Quick & Associates have any employees? 4 A. I'm the only person associated with 5 Quick & Associates for the consulting aspect. 6 Q. Okay. So no employees other than 7 potentially yourself? 8 A. That's correct. 9 Q. And are you -- you don't consider 10 yourself an employee of Quick & Associates? 11 A. That's correct. 12 Q. Your primary focus within Quick & 13 Associates has -- for the past few years, has been 14 with 503(a) and 503(b) compounding pharmacies. Is 15 that correct? 16 A. Among -- among other things. 17 Q. But you do state in your CV that the 18 primary focus in the past several years have been 19 with 503(a) and 503(b) compounding pharmacies. 20 Correct? 21 A. That -- that's what it says, but there 22 are a number of entities that I -- additional things 23 that I do. 24 Q. Okay. So is it your testimony that that 25 statement is not accurate?</p>
<p style="text-align: right;">Page 55</p> <p>1 A. That's correct. 2 Q. Does Quick & Associates have any 3 employees? 4 A. So, to clarify, Quick & Associates 5 includes other unrelated businesses associated not 6 with this, though, and there are employees of 7 that -- those businesses. 8 Q. When you say "not with this," what do you 9 mean by that? 10 A. Not associated with the consulting 11 business. 12 Q. Okay. And what businesses are those? 13 A. Those would be businesses that my wife 14 has related to equestrian matters. 15 Q. And those are housed under Quick & 16 Associates -- 17 A. That's right. 18 Q. -- as well? 19 A. They're sub -- they're sub -- they've got 20 subnames, but that they're -- they're not -- they're 21 separate. 22 Q. Would it be fair to refer to the 23 consulting division of Quick & Associates or was 24 there a better way to refer to that? 25 A. No, you can refer to Quick & Associates.</p>	<p style="text-align: right;">Page 57</p> <p>1 A. No, I'm not saying it's not accurate. 2 Q. Okay. So that has been your primary 3 focus, but there are other activities that you 4 engage in as well? 5 A. That's correct. 6 Q. On Page 3 of your CV, the second bullet 7 point says: Engaged as independent expert witness 8 on Q7A (API Quality). 9 What did that -- what did that matter 10 involve? 11 A. That's the matter we discussed earlier. 12 Q. Which one? We discussed a few. 13 A. This was with the firm in California who 14 was a contract manufacturer of monoclonal antibodies 15 and there was an issue with one of their customers 16 and I was called upon to prevent -- present an 17 expert testimony relative to Q7A at the time. 18 Q. And the next bullet point below that in 19 your CV says: Engaged as expert witness on aseptic 20 processing in a litigation case. 21 Which case was that? 22 A. That was a case we discussed that 23 occurred in 2012. 24 Q. And if you could just refresh my memory, 25 that case in 2012, was that the medical device case?</p>

15 (Pages 54 - 57)

<p style="text-align: right;">Page 58</p> <p>1 Was that a different case?</p> <p>2 A. The one in 2012 was the aseptic</p> <p>3 processing case between the two private equity</p> <p>4 firms.</p> <p>5 Q. Okay. Is -- is that the matter in</p> <p>6 connection with which you visited Teva or is that</p> <p>7 unrelated?</p> <p>8 A. It -- it's unrelated.</p> <p>9 Q. Okay. And then two bullet points down,</p> <p>10 do you see where it says: Have been preapproved by</p> <p>11 the FDA and DOJ to assist a drug company in a</p> <p>12 consent decree?</p> <p>13 A. I do.</p> <p>14 Q. What does that refer to?</p> <p>15 A. That refers to a company in St. Louis</p> <p>16 that had been notified that the Department of</p> <p>17 Justice wanted to enter into a consent decree with</p> <p>18 the company.</p> <p>19 Q. What do you mean when you say that you</p> <p>20 were "preapproved by the FDA and DOJ"?</p> <p>21 A. So they had to provide to DOJ and FDA an</p> <p>22 individual who would be their consultant in regard</p> <p>23 to this matter, which they did.</p> <p>24 Q. So they were free to choose?</p> <p>25 A. I'm sorry?</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. You've never worked for the FDA.</p> <p>2 Correct?</p> <p>3 A. No, I have not.</p> <p>4 Q. Looking at your list of papers,</p> <p>5 publications, presentations, and patents on Page 5,</p> <p>6 starting on Page 5 of your CV, Pages 5 and 6. The</p> <p>7 most recent one is November/December 2015. Is that</p> <p>8 correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And there hasn't been anything more</p> <p>11 recent than that that isn't reflected here?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. The items here are a mix of</p> <p>14 publications and oral presentations. Is that</p> <p>15 correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Did any of these relate to valsartan or</p> <p>18 valsartan-containing drugs?</p> <p>19 A. No, they did not.</p> <p>20 Q. Did any of these relate to nitrosamines?</p> <p>21 A. No, they did not.</p> <p>22 Q. Do you have any formal education in the</p> <p>23 regulatory or quality systems fields?</p> <p>24 A. Formal education, no.</p> <p>25 Q. Do any of your papers, publications, or</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. They were free to chose whomever they</p> <p>2 wished as a consultant?</p> <p>3 A. That's correct.</p> <p>4 Q. And they simply needed to inform FDA and</p> <p>5 DOJ who that was going to be?</p> <p>6 A. That's correct.</p> <p>7 Q. And the second bullet point from the</p> <p>8 bottom still on Page 3 of your CV, mentions:</p> <p>9 Continued to work with former boss (past Baxter</p> <p>10 chairman/CEO) and his private equity company focused</p> <p>11 on the FDA regulated industry.</p> <p>12 Who are you referring to there?</p> <p>13 A. Vernon Loucks. I would note that he's</p> <p>14 recently passed away.</p> <p>15 Q. Sorry to hear that.</p> <p>16 Okay. And prior to beginning your</p> <p>17 consulting practice through Quick & Associates, you</p> <p>18 were with Baxter for a number of years. Correct?</p> <p>19 A. That's correct.</p> <p>20 Q. From 1966 through 2003?</p> <p>21 A. That's correct.</p> <p>22 Q. Other than your consulting work, is your</p> <p>23 time at Baxter your only employment within the</p> <p>24 pharmaceutical and medical device industry?</p> <p>25 A. That's correct.</p>	<p style="text-align: right;">Page 61</p> <p>1 presentations relate to testing for impurities?</p> <p>2 A. No.</p> <p>3 Q. Do you currently hold any professional</p> <p>4 licenses?</p> <p>5 A. No.</p> <p>6 Q. And I know you testified earlier you've</p> <p>7 never been employed by FDA. Have you ever done any</p> <p>8 consulting for FDA?</p> <p>9 A. No.</p> <p>10 Q. You're not a toxicologist. Correct?</p> <p>11 A. No, I'm not.</p> <p>12 Q. You're not an epidemiologist?</p> <p>13 A. No, I'm not.</p> <p>14 Q. You're not a cancer biologist?</p> <p>15 A. No, I'm not.</p> <p>16 Q. You're not a statistician?</p> <p>17 A. No.</p> <p>18 Q. You're not an analytical chemist?</p> <p>19 A. I have a chemistry degree by education.</p> <p>20 Q. Okay. Do you consider yourself an</p> <p>21 analytical chemist?</p> <p>22 A. No.</p> <p>23 Q. Do you consider yourself an expert in</p> <p>24 pharmacovigilance?</p> <p>25 A. No.</p>

<p style="text-align: right;">Page 62</p> <p>1 Q. Are you a medical doctor?</p> <p>2 A. No.</p> <p>3 Q. Will you be offering any opinions in this</p> <p>4 litigation about how nitrosamines are absorbed in</p> <p>5 the human body?</p> <p>6 A. No, I am not.</p> <p>7 Q. Will you be offering any opinions in this</p> <p>8 litigation about how nitrosamines are metabolized by</p> <p>9 the human body?</p> <p>10 A. No, I will not.</p> <p>11 Q. Will you be offering any opinions in this</p> <p>12 litigation as to whether or not valsartan is an</p> <p>13 effective drug in the treatment of hypertension?</p> <p>14 A. No, I will not.</p> <p>15 Q. Would it be fair to say that your</p> <p>16 opinions in this litigation are limited to your</p> <p>17 analysis of CGMP protocols?</p> <p>18 MR. DAVIS: I'm going to object to</p> <p>19 the extent that that misrepresents his report.</p> <p>20 You can answer to the question.</p> <p>21 A. CGMP protocols, no. The answer is no.</p> <p>22 Q. Okay. How would you describe the scope</p> <p>23 of your opinions in this litigation?</p> <p>24 A. My opinions relate to the compliance</p> <p>25 aspects of the various companies related to CGMP as</p>	<p style="text-align: right;">Page 64</p> <p>1 Q. Does that --</p> <p>2 A. They could do that.</p> <p>3 Q. So they do have the power to do that?</p> <p>4 A. They --</p> <p>5 Q. Sorry. I just want to make sure that</p> <p>6 it's audible on the record. They do have the power</p> <p>7 to do that?</p> <p>8 A. They do have the power. Well, maybe I</p> <p>9 should elaborate here, because that's not really the</p> <p>10 case.</p> <p>11 If the FDA believes a recall should</p> <p>12 happen, they will say -- they will tell the firm</p> <p>13 that they recommend that the firm recall a product,</p> <p>14 and then the firm will voluntarily recall a product,</p> <p>15 usually.</p> <p>16 Q. Does the FDA have the option of obtaining</p> <p>17 an injunction?</p> <p>18 A. Going through the Department of Justice,</p> <p>19 yes.</p> <p>20 Q. And does the FDA have the ability to stop</p> <p>21 a manufacturer from distributing a product?</p> <p>22 A. If they go through the Department of</p> <p>23 Justice, they would have that authority.</p> <p>24 Q. Does FDA have the power to seize product?</p> <p>25 A. They do. It's not -- I'm not certain</p>
<p style="text-align: right;">Page 63</p> <p>1 it pertains to the whole class action.</p> <p>2 Q. Anything else?</p> <p>3 A. It's -- it was the GMP aspects.</p> <p>4 Q. And you won't be offering any causation</p> <p>5 opinions in this litigation. Correct?</p> <p>6 MR. DAVIS: I'm going to object to</p> <p>7 the question.</p> <p>8 You can answer.</p> <p>9 A. Would you like to explain that?</p> <p>10 Q. Sure.</p> <p>11 You're not going to be offering any</p> <p>12 opinions in this litigation on whether defendants'</p> <p>13 products caused or contributed to any of plaintiffs'</p> <p>14 alleged injuries. Correct?</p> <p>15 A. No, I'm not.</p> <p>16 Q. Would it be fair to say that FDA plays an</p> <p>17 active role in regulation of pharmaceuticals and</p> <p>18 manufacture of pharmaceuticals?</p> <p>19 A. Plays a role? Yes, that would be fair.</p> <p>20 Q. And the FDA has a spectrum of available</p> <p>21 enforcement options. Correct?</p> <p>22 A. Correct.</p> <p>23 Q. That includes ordering a recall?</p> <p>24 A. So, typically, FDA would not order a</p> <p>25 recall.</p>	<p style="text-align: right;">Page 65</p> <p>1 whether they have to go through the Department of</p> <p>2 Justice to seize the product or not, but they would</p> <p>3 typically do that, I believe. They do seize</p> <p>4 product.</p> <p>5 Q. And does the FDA have the power to pursue</p> <p>6 criminal prosecution?</p> <p>7 A. In conjunction with the Department of</p> <p>8 Justice, yes.</p> <p>9 Q. Now, in your report, you discuss various</p> <p>10 FDA guidelines. Correct?</p> <p>11 A. Guidances.</p> <p>12 Q. Okay. Only guidances, no guidelines?</p> <p>13 MR. DAVIS: I'll object to the</p> <p>14 question as vague.</p> <p>15 A. So I'm not sure what I reference to what</p> <p>16 are guidelines. It's typically guidances.</p> <p>17 Q. Okay. And is it your understanding that</p> <p>18 the terms "guidance" and "guideline" are distinct in</p> <p>19 discussing FDA -- in the FDA context?</p> <p>20 A. Well, typically, it's guidances. I'm</p> <p>21 not -- if -- we'd have to -- we'd have to talk about</p> <p>22 what you mean, "guidelines."</p> <p>23 Q. Are you familiar with FDA ever having</p> <p>24 issued something that is a guideline, rather than a</p> <p>25 guidance?</p>

<p style="text-align: right;">Page 66</p> <p>1 A. Maybe. I don't recall.</p> <p>2 Q. 21 CFR 210 and 21 CFR 211 set forth the</p> <p>3 CGMP for pharmaceutical products. Correct?</p> <p>4 A. That's correct.</p> <p>5 Q. And several of your opinions in this case</p> <p>6 refer to 21 CFR 210 and 211. Correct?</p> <p>7 A. Correct.</p> <p>8 Q. Is it fair to say that how a particular</p> <p>9 company achieves the controls described in 21 CFR</p> <p>10 210 and 211 is up to the company to decide.</p> <p>11 Correct?</p> <p>12 MR. DAVIS: Object to form.</p> <p>13 A. As long as they're compliant.</p> <p>14 Q. 21 CFR 210 and 21 CFR 211 don't set forth</p> <p>15 specific instructions on how to achieve the controls</p> <p>16 that are described therein. Right?</p> <p>17 MR. DAVIS: Object to form.</p> <p>18 A. The FDA -- FDA does describe those in the</p> <p>19 guidances that they have in terms of how you meet</p> <p>20 the requirements of 21 CFR 210 and 211.</p> <p>21 Q. So focusing solely on 21 CFR 210 and</p> <p>22 21 CFR 211, those do not set forth specific</p> <p>23 instructions on how to achieve the controls that are</p> <p>24 described therein. Right?</p> <p>25 A. As you stated it, you're correct.</p>	<p style="text-align: right;">Page 68</p> <p>1 A. So 210 and 211 cover a wide variety, a</p> <p>2 wide range of aspects, okay, and so for almost all</p> <p>3 of those, there would be a guidance.</p> <p>4 Q. Okay. As you sit here today, can you --</p> <p>5 A. Sure.</p> <p>6 Q. -- identify one?</p> <p>7 A. Sure.</p> <p>8 FDA has a guidance on process validation.</p> <p>9 Q. Okay. And what is that guidance?</p> <p>10 MR. DAVIS: Are you asking for the</p> <p>11 cite or?</p> <p>12 MS. ISIDRO: Yes.</p> <p>13 A. So what do you mean, "what is that</p> <p>14 guidance," what --</p> <p>15 Q. Is there a formal title or a citation for</p> <p>16 that guidance?</p> <p>17 A. I don't -- it's -- process validation is</p> <p>18 the guidance.</p> <p>19 Q. Okay. And does that guidance provide</p> <p>20 specific instructions on how to achieve the controls</p> <p>21 that are described with respect to process</p> <p>22 validation in 21 CFR 210 and 211?</p> <p>23 MR. DAVIS: I'm going to -- same</p> <p>24 objection, and vague as to your use of the term</p> <p>25 "specific instructions."</p>
<p style="text-align: right;">Page 67</p> <p>1 MR. DAVIS: I'm going to object to</p> <p>2 that.</p> <p>3 THE WITNESS: I'm sorry.</p> <p>4 MR. DAVIS: Give me a few moments to</p> <p>5 object.</p> <p>6 Q. Now, you mentioned a moment ago that FDA</p> <p>7 describes in guidances how you meet the requirements</p> <p>8 of 21 CFR 210 and 211. Is that correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And what guidances are you referring to?</p> <p>11 A. FDA has thousands of guidances, so I --</p> <p>12 it's not just one guidance, there is -- there are</p> <p>13 many guidances.</p> <p>14 Q. Are there any that you can think of, as</p> <p>15 you sit here today, that provide specific</p> <p>16 instructions on how to achieve the controls in</p> <p>17 21 CFR 210?</p> <p>18 A. There is gui- -- FDA has guidances on</p> <p>19 almost every aspect of 210 and 211, so...</p> <p>20 Q. Okay. But as you sit here today, can you</p> <p>21 think of a guidance that set forths -- that sets</p> <p>22 forth specific instructions on how to achieve the</p> <p>23 controls that are described in 21 CFR 210?</p> <p>24 MR. DAVIS: Object to form.</p> <p>25 You can answer.</p>	<p style="text-align: right;">Page 69</p> <p>1 But you can answer.</p> <p>2 A. It provides the guidance on how to</p> <p>3 conduct proper process validations for drug</p> <p>4 companies.</p> <p>5 Q. Okay. So let me ask you this: Would a</p> <p>6 drug company be able to take the FDA guidance on</p> <p>7 process validation and implement it without having</p> <p>8 any manufacturer-specific processes or details</p> <p>9 included or added?</p> <p>10 MR. DAVIS: Object to form.</p> <p>11 A. So what a company should do would be they</p> <p>12 would develop standard operating procedures on how</p> <p>13 to meet the requirements and the guidances.</p> <p>14 Q. And those standing -- standard operating</p> <p>15 procedures are a necessary part of the process for</p> <p>16 compliance with 21 CFR 210 and 211. Correct?</p> <p>17 A. Correct.</p> <p>18 Q. And those SOPs -- is it okay if we refer</p> <p>19 to standard operating procedures as SOPs?</p> <p>20 A. Sure.</p> <p>21 Q. Okay. Those SOPs would be drafted by</p> <p>22 each individual manufacturer. Correct?</p> <p>23 A. Correct.</p> <p>24 Q. They're not something that is issued in a</p> <p>25 standard format by FDA, ready to implement?</p>

<p style="text-align: right;">Page 70</p> <p>1 A. That's correct.</p> <p>2 Q. Okay. Your report discusses Form 483s.</p> <p>3 Correct?</p> <p>4 A. That's correct.</p> <p>5 Q. FDA can sometimes inspect a</p> <p>6 manufacturer's facility. Right?</p> <p>7 A. That's correct.</p> <p>8 Q. And that's commonly referred to as an FDA</p> <p>9 site inspection?</p> <p>10 A. Yes.</p> <p>11 Q. And upon conclusion of a site inspection</p> <p>12 by FDA, the FDA investigator may issue a Form</p> <p>13 FDA 483, based on what was observed during the</p> <p>14 inspection. Correct?</p> <p>15 A. That's correct.</p> <p>16 Q. Would you agree that Form 483s are</p> <p>17 relatively common in the industry?</p> <p>18 MR. DAVIS: Object to form.</p> <p>19 A. Well, the term -- what do you mean,</p> <p>20 "relatively common"? Many companies do not get a</p> <p>21 Form 483 after an inspection.</p> <p>22 Q. During your time at Baxter, did they ever</p> <p>23 receive a Form 483?</p> <p>24 A. Yes.</p> <p>25 Q. And an FDA Form 483 is a list of</p>	<p style="text-align: right;">Page 72</p> <p>1 follow a Form 483. Correct?</p> <p>2 A. That is correct.</p> <p>3 Q. Are Form 483s and warning letters issued</p> <p>4 by the same division within FDA?</p> <p>5 A. I'm not sure I know what you mean by</p> <p>6 "division."</p> <p>7 Typically the drug group would handle the</p> <p>8 drug aspects. You wouldn't get a warning letter on</p> <p>9 a drug product from the medical device group, for</p> <p>10 example.</p> <p>11 Q. Okay. Are you familiar with the Office</p> <p>12 of Regulatory Affairs within FDA?</p> <p>13 A. Yes.</p> <p>14 Q. Does the Office of Regulatory Affairs</p> <p>15 issue Form 483s?</p> <p>16 A. They can.</p> <p>17 Q. Does the Office of Regulatory Affairs</p> <p>18 issue warning letters?</p> <p>19 A. They can. Typically it would come from</p> <p>20 the local office -- or the district office or</p> <p>21 regional office.</p> <p>22 Q. Are you familiar with the FDA's</p> <p>23 regulatory procedures manual?</p> <p>24 A. I've seen it, yes. I've looked at it,</p> <p>25 I've reviewed it. It's extensive.</p>
<p style="text-align: right;">Page 71</p> <p>1 observations made by the FDA inspector during the</p> <p>2 inspection and presented to the most responsible</p> <p>3 person of the inspected facility at the close of the</p> <p>4 inspection. Correct?</p> <p>5 A. Correct.</p> <p>6 Q. FDA 483 inspectional observations are</p> <p>7 considered to be the opinion of the FDA</p> <p>8 investigator. Correct?</p> <p>9 MR. DAVIS: Object to form.</p> <p>10 A. Typically, before a FDA 483 is issued,</p> <p>11 the investigator will confer with the center or his</p> <p>12 office before issuing that. So it would be probably</p> <p>13 the opinion of the investigator, but also conferring</p> <p>14 with the office.</p> <p>15 Q. FDA Form 483s do not represent a final</p> <p>16 agency determination regarding compliance. Correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Your report also discusses warning</p> <p>19 letters. Is that right?</p> <p>20 A. That's correct.</p> <p>21 Q. A warning letter is sometimes issued by</p> <p>22 the FDA as a result of an inspection and issuance of</p> <p>23 a Form 483?</p> <p>24 A. That's correct.</p> <p>25 Q. But a warning letter does not always</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. And are you aware that the FDA's</p> <p>2 regulatory procedure manual states that a warning</p> <p>3 letter is informal and advisory?</p> <p>4 A. I think it says more than that, but we'd</p> <p>5 have to go back and look at exactly what it says.</p> <p>6 Q. Would it be fair to say that a warning</p> <p>7 letter communicates the agency's position on a</p> <p>8 matter, but it does not commit the FDA to taking</p> <p>9 enforcement action?</p> <p>10 MR. DAVIS: Object to form.</p> <p>11 A. It does not commit the FDA to take an</p> <p>12 enforcement action beyond that.</p> <p>13 Q. And the FDA itself does not consider</p> <p>14 warning letters to be final agency action on which</p> <p>15 it can be sued. Is that correct?</p> <p>16 MR. DAVIS: Object to form.</p> <p>17 A. There are additional actions beyond the</p> <p>18 warning letter.</p> <p>19 Q. After a warning letter is issued, the FDA</p> <p>20 reviews a manufacturer's response to the warning</p> <p>21 letter. Correct?</p> <p>22 A. Usually.</p> <p>23 Q. And what do you mean by "usually"?</p> <p>24 A. I mean, they can take action without</p> <p>25 reviewing that.</p>

<p style="text-align: right;">Page 74</p> <p>1 Q. What sorts of actions could they take 2 without reviewing that?</p> <p>3 A. Well, they could go directly to some sort 4 of a consent decree or seizures or some other 5 action, depending on what it is. But they would 6 usually review the warning letter response.</p> <p>7 I will note, though, in many warning 8 letters they will put the fact that they're going to 9 initiate an import detention for those firms that 10 reside outside the United States in the warning 11 letter.</p> <p>12 Q. What does that entail?</p> <p>13 A. That means that those products from that 14 company cannot be imported to the United States.</p> <p>15 Q. So when the FDA reviews a company's 16 response to a warning letter, if the FDA is 17 satisfied with the company's response, does it close 18 out the warning letter?</p> <p>19 MR. DAVIS: Object to form.</p> <p>20 A. No, not usually.</p> <p>21 Q. So what happens once the FDA has reviewed 22 a company's response to a warning letter and the FDA 23 is satisfied with the response?</p> <p>24 A. They won't be satisfied until they come 25 back for an additional inspection, usually.</p>	<p style="text-align: right;">Page 76</p> <p>1 sources did you use to learn about nitrosamines in 2 connection with this litigation?</p> <p>3 A. I reviewed the documents that were 4 provided by the company in response to my request.</p> <p>5 Q. And when you say "the documents that were 6 provided by the company," what company are you 7 referring to?</p> <p>8 A. The defendants.</p> <p>9 Q. So you reviewed documents produced by the 10 defendants in this litigation?</p> <p>11 A. I did.</p> <p>12 Q. Did the documents that you reviewed 13 include information about levels of impurities found 14 in each manufacturer's product?</p> <p>15 A. Well, we're talking a number of 16 defendants. Some did, yes.</p> <p>17 Q. Did you review nitrosamine levels for 18 each defendant's products?</p> <p>19 A. No. What I was tasked to do was to 20 determine the CGMP compliance of the various 21 companies.</p> <p>22 Q. And does that mean that you do -- you 23 would not view the levels of nitrosamines in the 24 product as relevant to that inquiry?</p> <p>25 MR. DAVIS: Object to form;</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. And what is that based on, your statement 2 that they won't be satisfied usually until they come 3 back for an inspection?</p> <p>4 (Simultaneous speaking.)</p> <p>5 A. The typical action by the FDA, in order 6 to close out a warning letter, is that they will 7 come back and do an inspection. That's the typical 8 response from the FDA.</p> <p>9 Q. And when you say "that's the typical 10 response from the FDA," is that based on your 11 experience?</p> <p>12 A. Yes.</p> <p>13 Q. Based on anything else?</p> <p>14 A. Well, it's based on what they do. It's 15 just history.</p> <p>16 Q. So just what you've observed over the 17 years in this industry?</p> <p>18 A. Yes.</p> <p>19 Q. In your report in this litigation you 20 refer to nitrosamines. Correct?</p> <p>21 A. I do.</p> <p>22 Q. And are the nitrosamines you're referring 23 to NDMA and NDEA?</p> <p>24 A. Yes.</p> <p>25 Q. What sources did you learn to -- what</p>	<p style="text-align: right;">Page 77</p> <p>1 mischaracterizes his testimony.</p> <p>2 A. Well, they're probably relevant because 3 that's the basis for many of the issues that the FDA 4 had with the companies.</p> <p>5 Q. So you did not review nitrosamine levels 6 for each defendant's products, but you do view that 7 information as relevant to your opinions?</p> <p>8 MR. DAVIS: Object to form; 9 mischaracterizes his testimony.</p> <p>10 A. No, I don't consider it to be relevant. 11 What I consider to be relevant are the CGMP aspects 12 of the various companies. That was one component of 13 it, but it wasn't the determining factor for CGMP.</p> <p>14 MS. ISIDRO: Let's go ahead and take 15 a short break, five minutes.</p> <p>16 MR. DAVIS: Sure.</p> <p>17 THE VIDEOGRAPHER: Off the record. 18 The time is 11:33 a.m.</p> <p>19 (Break.)</p> <p>20 THE VIDEOGRAPHER: We're back on the 21 record at 11:46 a.m.</p> <p>22 Q. Mr. Quick, one of the documents that you 23 relied on in your report was the FDA's guidance to 24 manufacturers of human drugs on controlled 25 nitrosamine impurities. Correct?</p>

<p style="text-align: right;">Page 78</p> <p>1 A. If I reference -- I have to go back and 2 look. If I reference it there, yes. I don't recall 3 that, but, yes. 4 Q. Well, let's take a look at your reliance 5 list in your report. 6 A. Yes, I do see it. 7 Q. Okay. It's on Page 3, right, the second 8 item from the top? 9 A. Right. 10 Q. Yeah. Okay. Now, that guidance was not 11 released until 2021. Correct? 12 A. Yes. That's the date that's stated here. 13 I don't know whether there is an earlier version of 14 it or not, but... 15 Q. Okay. So as you sit here right now, you 16 don't know one way or the other whether there was an 17 earlier version of the FDA's guidance on control of 18 nitrosamine impurities in human drugs? 19 MR. DAVIS: I'm going to object to 20 form and vague and ambiguous for draft or final. 21 A. I'm not certain. 22 Q. Are you aware of whether the FDA had set 23 any interim limits on nitrosamines? 24 A. I didn't -- I didn't review the limits 25 that the FDA has set. What I was reviewing were the</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Well, it's a requirement for under Q7A 2 that you would know your impurity profiles. 3 Q. And where would impurity profiles for a 4 particular product be set forth? 5 A. I didn't catch the last part of that. 6 MS. ISIDRO: Can you read it back, 7 please? 8 (The requested material was read.) 9 A. Well, the manufacturer is supposed to set 10 forth their own impurity profiles. 11 Q. And where would the manufacturer do that? 12 Is that part of a submission to the FDA? 13 A. It could be, but they're supposed to know 14 their own impurity profiles. I mean -- so the FDA 15 would not know what those are. The manufacturers 16 would know or should know. 17 Q. Okay. And are there specific standards 18 that are set forth for the composition of a 19 particular drug product? 20 MR. DAVIS: Object to form. 21 You can answer. 22 A. Well, there are USP monographs. And the 23 FDA -- the firms would put into their files what 24 they're going to do and the FDA would determine 25 whether those are acceptable for that or not.</p>
<p style="text-align: right;">Page 79</p> <p>1 CGMP aspects as it applied to all of the class 2 group. That's what I was reviewing. And the 3 particular limits of the nitrosamine was not 4 relevant to the CGMP aspect. 5 Q. So as you sit here today you don't know 6 one way or the other whether there was an FDA 7 standard requiring testing for nitrosamines in the 8 2012 to 2018 period? 9 A. There was a requirement for the 10 manufacturers to know their impurities and to 11 characterize the impurities that they would find in 12 the product. 13 Q. But as you sit here today, you don't know 14 one way or the other whether the FDA had a standard 15 requiring testing for nitrosamine specifically in 16 2012 to 2018? 17 MR. DAVIS: I'm going to object to 18 the form. 19 A. Again, as I stated, the FDA's expectation 20 was that the manufacturers would characterize the 21 impurities and define the impurities. That was the 22 expectation. 23 Q. Would that be part of the compendial 24 standards for a product? 25 MR. DAVIS: Object to form.</p>	<p style="text-align: right;">Page 81</p> <p>1 But I don't know. There's -- I'm not 2 sure I understand exactly your use of the word 3 "standards." 4 Q. Sure. Does USP set forth testing 5 requirements for impurities in a particular drug 6 product? 7 MR. DAVIS: Object to form; 8 Incomplete question. 9 A. They may. I'm not certain. But Q7 does. 10 That was the real point. 11 Q. What determines the particular impurities 12 that a manufacturer has to test for with respect to 13 a specific drug product? 14 MR. DAVIS: Objection; vague. Are 15 you referring to impurities or genotoxic impurities? 16 Q. You can answer the question. 17 A. Sorry. Would you repeat the question? 18 MS. ISIDRO: Can you read it back, 19 please? 20 (The requested material was read.) 21 Q. That's -- 22 MR. DAVIS: Same objection; vague. 23 A. Manufacturer is supposed to characterize 24 their impurities and know what they are. 25 Q. How does that get implemented into the</p>

<p style="text-align: right;">Page 82</p> <p>1 manufacturing process?</p> <p>2 MR. DAVIS: Object to form. That --</p> <p>3 vague.</p> <p>4 A. I'm not sure I understand what you're</p> <p>5 trying to go with, with that.</p> <p>6 Q. So it's your testimony that a -- it's our</p> <p>7 testimony that a manufacturer is supposed to</p> <p>8 characterize the impurities associated with a</p> <p>9 particular drug product to know what they are.</p> <p>10 Correct?</p> <p>11 A. That's correct.</p> <p>12 Q. What happens once a manufacturer</p> <p>13 identifies impurities during that process?</p> <p>14 A. Well, it depends what the impurities are</p> <p>15 and determines what actions they should take. They</p> <p>16 need to know what they are in the first place.</p> <p>17 Q. Okay. Are you familiar with the concept</p> <p>18 of compendial standards for a pharmaceutical</p> <p>19 product?</p> <p>20 A. Compendial products? Are we talking</p> <p>21 about USP? Is that what we're talking about?</p> <p>22 Q. Just -- is -- is that what it means to</p> <p>23 you?</p> <p>24 MR. DAVIS: If he --</p> <p>25 A. I don't use that term.</p>	<p style="text-align: right;">Page 84</p> <p>1 A. No, I -- I didn't say that. I'm saying I</p> <p>2 just didn't review that.</p> <p>3 Q. Okay.</p> <p>4 A. The -- the other thing I would add is</p> <p>5 what I have in the report are examples. It's not an</p> <p>6 exhaustive list.</p> <p>7 Q. We're going to get to the examples in</p> <p>8 your report in -- in due course.</p> <p>9 Are you aware that in 2018 FDA stated</p> <p>10 that: The presence of NDMA was unexpected and was</p> <p>11 thought to be related to changes in the way active</p> <p>12 substance was manufactured?</p> <p>13 MR. DAVIS: Object to form.</p> <p>14 A. I don't recall that exact term.</p> <p>15 Q. Did you review the July 2018 statements</p> <p>16 that FDA issued regarding nitrosamines?</p> <p>17 A. I may have. I don't recall those.</p> <p>18 MR. DAVIS: And I'll object to that</p> <p>19 as vague. There were plenty of statements from the</p> <p>20 FDA in 2018.</p> <p>21 MS. ISIDRO: I'm going to mark as</p> <p>22 Exhibit 8 an August 30, 2018, statement from FDA on</p> <p>23 FDA's ongoing investigation into valsartan</p> <p>24 impurities and recalls and an update on FDA's</p> <p>25 current findings.</p>
<p style="text-align: right;">Page 83</p> <p>1 MR. DAVIS: He's asking for a</p> <p>2 clarification.</p> <p>3 Q. What term do you use?</p> <p>4 A. USP monographs.</p> <p>5 Q. USP monographs.</p> <p>6 Are impurities addressed within USP</p> <p>7 monographs for a direct product?</p> <p>8 MR. DAVIS: Objection to form and</p> <p>9 vague as to the use of the word "impurities."</p> <p>10 A. I'd have to go back and review that. The</p> <p>11 key point is they're addressed in Q7 as to -- as to</p> <p>12 what a manufacturer should do.</p> <p>13 Q. As you sit here today, do you know</p> <p>14 whether any -- do you know whether USP monographs</p> <p>15 for any valsartan-containing product set forth any</p> <p>16 standard for testing for nitrosamines in the 2012 to</p> <p>17 2018 time period?</p> <p>18 MR. DAVIS: Object to form.</p> <p>19 You can answer.</p> <p>20 A. I didn't review that and it wasn't</p> <p>21 necessary to review that based on the fact that I</p> <p>22 was looking at the CGMP aspects as it pertained to</p> <p>23 the class group.</p> <p>24 Q. Okay. So you did not view USP monographs</p> <p>25 as relevant to the scope of your opinions?</p>	<p style="text-align: right;">Page 85</p> <p>1 (Exhibit 8 was marked.)</p> <p>2 Q. Have you seen this document before,</p> <p>3 Mr. Quick?</p> <p>4 A. I may have, I'm not certain.</p> <p>5 Q. As you sit here today, you can't recall</p> <p>6 one way or the other?</p> <p>7 A. Well, there are a lot of documents on</p> <p>8 this subject so I may have seen this.</p> <p>9 Q. But you don't recall specifically as you</p> <p>10 sit here today?</p> <p>11 A. I don't recall specifically this</p> <p>12 document.</p> <p>13 Q. I'm going to turn your attention to the</p> <p>14 third page of this press -- of this statement,</p> <p>15 excuse me. And I'm going to draw your attention to</p> <p>16 the second paragraph from -- excuse me.</p> <p>17 I'm actually going to draw your attention</p> <p>18 to the last paragraph at the bottom of that page.</p> <p>19 About halfway through that do you see where it says:</p> <p>20 Before we undertook this analysis, neither</p> <p>21 regulators in our industry fully understood how NDMA</p> <p>22 could form during this process?</p> <p>23 A. I see that.</p> <p>24 Q. So this was not something that FDA</p> <p>25 understood --</p>

<p style="text-align: right;">Page 86</p> <p>1 MR. DAVIS: Object to form.</p> <p>2 Q. -- previously?</p> <p>3 MR. DAVIS: And calls for speculation</p> <p>4 as well.</p> <p>5 A. Well, I'm not going to speak for FDA. I</p> <p>6 can read this -- what it said. What it stated here.</p> <p>7 Q. Is it your understanding that FDA is</p> <p>8 saying that is -- it is acknowledging that it did</p> <p>9 not understand it previously?</p> <p>10 MR. DAVIS: Object to form, and calls</p> <p>11 for speculation.</p> <p>12 A. That -- that -- I'll read you what it</p> <p>13 saws here: Before we undertook this analysis,</p> <p>14 neither regulators in our industry understood how</p> <p>15 NDMA could form during this process.</p> <p>16 That's what it says.</p> <p>17 Q. And, in fact, FDA did not initially have</p> <p>18 the analytical capability to measure nitrosamine</p> <p>19 impurities. Isn't that right?</p> <p>20 MR. DAVIS: Object to form.</p> <p>21 A. I don't know.</p> <p>22 Q. Well, let's take a look at the second</p> <p>23 full paragraph on the third page of this statement.</p> <p>24 That references F -- the fact that: In St. Louis</p> <p>25 the FDA maintains the most advanced pharmaceutical</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. Are current industry standards relevant</p> <p>2 to current good manufacturing processes?</p> <p>3 MR. DAVIS: Object to form.</p> <p>4 You can answer if you understand it.</p> <p>5 A. If you want to talk about industry, what</p> <p>6 industry standards you're referring to?</p> <p>7 Q. Are pharmaceutical industry standards</p> <p>8 relevant to current good manufacturing practices in</p> <p>9 the pharmaceutical industry?</p> <p>10 A. So you need to describe what you mean by</p> <p>11 pharmaceutical standards, industry standards.</p> <p>12 That's not -- that's not a typical term that would</p> <p>13 be used.</p> <p>14 Q. Okay. Are current testing capabilities</p> <p>15 relevant to the question of current good</p> <p>16 manufacturing practices in the pharmaceutical</p> <p>17 industry?</p> <p>18 A. Probably not.</p> <p>19 Q. Why not?</p> <p>20 A. Because we're talking about current good</p> <p>21 manufacturing practices, we're not talking about</p> <p>22 testing methods.</p> <p>23 Q. Testing methods are completely irrelevant</p> <p>24 to good manufacturing practices?</p> <p>25 A. I did not say that.</p>
<p style="text-align: right;">Page 87</p> <p>1 laboratory of any regulatory agency in the world.</p> <p>2 Correct?</p> <p>3 A. That's what it says.</p> <p>4 Q. And further down in the paragraph it</p> <p>5 states that: To determine if valsartan products do</p> <p>6 contain the NDMA impurity, CDER scientists have now</p> <p>7 developed the gas chromatography mass spectrometry</p> <p>8 head space testing method.</p> <p>9 Correct?</p> <p>10 MR. DAVIS: Are you asking if he sees</p> <p>11 that?</p> <p>12 A. I see that, yes, if that's what you're</p> <p>13 asking.</p> <p>14 Q. So, in fact, FDA scientists had to</p> <p>15 develop a new method in order to determine whether</p> <p>16 valsartan products contained NDMA?</p> <p>17 MR. DAVIS: Object to form, and</p> <p>18 mischaracterizes the statement.</p> <p>19 A. I'm not -- I'm not going to say I --</p> <p>20 MR. DAVIS: Let me finish my</p> <p>21 objection first. Yeah. Object to form, and</p> <p>22 mischaracterizes the statement in the document.</p> <p>23 You -- you can answer. It's okay.</p> <p>24 A. So I see what it says here, but I'm not</p> <p>25 going to speak for the FDA.</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. Okay. Then help me understand why,</p> <p>2 because we're talking about current good</p> <p>3 manufacturing practices and not testing methods,</p> <p>4 testing capabilities are not relevant to current</p> <p>5 good manufacturing practices?</p> <p>6 MR. DAVIS: Object to the form, and</p> <p>7 mischaracterizes his testimony.</p> <p>8 A. Testing capabilities and good</p> <p>9 manufacturing practices are two different things.</p> <p>10 Q. Okay. Is -- they are two different</p> <p>11 things. Are they relevant to each other?</p> <p>12 MR. DAVIS: Objection; vague.</p> <p>13 You can answer.</p> <p>14 A. I'm not going to say there's no</p> <p>15 relevance, but I'm just saying they're two different</p> <p>16 things.</p> <p>17 Q. If a test doesn't exist, can it form part</p> <p>18 of current good manufacturing practices?</p> <p>19 A. Well, if a -- what you said makes no</p> <p>20 sense.</p> <p>21 MR. DAVIS: Object to the</p> <p>22 hypothetical, is contrary to --</p> <p>23 A. What you just stated really makes no</p> <p>24 sense.</p> <p>25 Q. Why doesn't it make sense?</p>

<p style="text-align: right;">Page 90</p> <p>1 A. If something doesn't exist -- you want to 2 elaborate more what you're trying to say? 3 Q. Well, if something doesn't exist, it 4 can't form part of good -- current good 5 manufacturing practices. Right? 6 MR. DAVIS: Object to form, and 7 presenting an improper hypothetical. 8 A. I'm not sure where -- where you're going 9 with this, but they're not relevant to each other 10 based on what you're saying. 11 Q. So you won't agree with me that if 12 something doesn't exist, it cannot form part of 13 current good manufacturing practices? 14 MR. DAVIS: Object to form, that 15 mischaracterizations his testimony. 16 You can answer. 17 A. If some -- if something doesn't exist, 18 then it obviously wouldn't be part of anything. 19 Q. What is your understanding of adulterated 20 products in the context of pharmaceutical regulatory 21 compliance? 22 A. If a firm fails to meet CGMPs -- there 23 are several aspects. If a firm fails to meet CGMPs, 24 the product -- the products that they make in that 25 facility would be considered -- would be considered</p>	<p style="text-align: right;">Page 92</p> <p>1 current good manufacturing practices, the products 2 are adulterated. 3 Q. Is there a particular regulation or other 4 place where FDA defines adulterated product? 5 A. It states it many places. And I think I 6 reference those in the report. 7 Q. Okay. Can -- do you still have your 8 report -- 9 A. Yes. 10 Q. -- in front of you? 11 Can you show me where you reference that? 12 A. Okay. We'll have to go through here and 13 find it. 14 (Pause.) 15 Well, Section -- my Section 24 refers to 16 that. 17 MR. DAVIS: For the record, are you 18 on Page 6, Mr. Quick? 19 THE WITNESS: Yes, on Page 6. 20 MR. DAVIS: Okay. 21 Q. Does FDA also define the term 22 "misbranded"? 23 MR. DAVIS: Object -- 24 A. That's separate. 25 MR. DAVIS: Hang on, Mr. Quick. Let</p>
<p style="text-align: right;">Page 91</p> <p>1 to be adulterated. 2 Q. That is your complete understanding of 3 the term "adulterated products" in the 4 pharmaceutical context? 5 A. No -- 6 MR. DAVIS: Object to form, if you 7 want him to look at his report, he's willing to look 8 at his report. 9 A. Yeah. I -- I -- I go into that in the 10 report. There are other aspects of adulteration. 11 Q. My question to you what is -- was, what 12 is your understanding of the term "adulterated 13 products" in the pharmaceutical context? 14 MR. DAVIS: Object to form. 15 You can answer. 16 A. So a product could be contaminated, that 17 would be adulteration. Or the product could be fine 18 but if the firm failed to adhere to current good 19 manufacturing practices, the products that they are 20 making, by definition are adulterated. 21 Q. Does FDA define adulterated products? 22 A. I just defined it. 23 Q. My question was, does FDA define it? 24 A. They do. The FDA states if the firm is 25 not manufacturing products in accordance with the</p>	<p style="text-align: right;">Page 93</p> <p>1 me place an objection on the record. 2 So I'm going to object to form, and 3 vague as to your term -- use of the term "FDA 4 defining" something. 5 You can answer, Mr. Quick. 6 THE WITNESS: So what was -- 7 MS. ISIDRO: If you could read back 8 the question and the answer that Mr. Quick started 9 to give before the objection. 10 (The requested material was read.) 11 A. So I'm not sure I understand the 12 question. 13 Q. Well, you said "That's separate." What 14 do you mean? 15 A. Yeah, I -- that was, like, five minutes 16 ago. So, I mean, you may want to rephrase your 17 question. 18 Q. Does FDA define the term "misbranded" in 19 the pharmaceutical context? 20 MR. DAVIS: Object to form, and same 21 objection as to the use of the word "FDA defining" 22 something. 23 A. Well, I've discussed misbranding in the 24 report here, and we can probably pull that up. 25 (Pause.)</p>

<p style="text-align: right;">Page 94</p> <p>1 So relative to misbranding, on 27: A</p> <p>2 drug product may be declared misbranded if the label</p> <p>3 is false or misleading in any -- in a way which</p> <p>4 fails to reveal facts material with respect to</p> <p>5 consequences which may result from use of the</p> <p>6 article.</p> <p>7 There may be another place, too.</p> <p>8 (Pause.)</p> <p>9 Q. You said there may be another place, too.</p> <p>10 Did you find another place?</p> <p>11 A. There may be, but I think that covers it.</p> <p>12 Q. Okay. What do you understand to be the</p> <p>13 difference between the terms "adulterated" and</p> <p>14 "misbranded" in the pharmaceutical context?</p> <p>15 A. Well, if a product is misbranded, it's</p> <p>16 considered to be adulterated. Adulterated product</p> <p>17 doesn't necessarily have to be misbranded.</p> <p>18 Q. Can you explain that further?</p> <p>19 A. What would you like me to explain?</p> <p>20 Q. Well, is that the only difference between</p> <p>21 the terms?</p> <p>22 A. Well, as I said a few minutes ago, is I</p> <p>23 explained to you how a product can be considered to</p> <p>24 be adulterated.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 96</p> <p>1 statement exactly?</p> <p>2 (Discussion off the written record.)</p> <p>3 (The requested material was read.)</p> <p>4 MR. DAVIS: Thank you.</p> <p>5 So what's -- is there a question</p> <p>6 pending right now?</p> <p>7 MS. ISIDRO: Can you read back the</p> <p>8 last question, please?</p> <p>9 (The requested material was read.)</p> <p>10 A. So as I've indicated, the FDA states</p> <p>11 that. They also -- in almost virtually every</p> <p>12 warning letter that's issued to a firm, they will</p> <p>13 say in the warning letter that the product is</p> <p>14 considered to be adulterated because CMG -- CM --</p> <p>15 they were in violation of CGMPs.</p> <p>16 Q. Can you point to any warning letters</p> <p>17 where FDA says that one product is adulterated</p> <p>18 because of CGMP violations in connection with a</p> <p>19 different product?</p> <p>20 A. So -- okay.</p> <p>21 (Pause.)</p> <p>22 Well, the examples in the warning letters</p> <p>23 refer to the facility. They don't refer to specific</p> <p>24 products.</p> <p>25 So, I mean, we could pull up any warning</p>
<p style="text-align: right;">Page 95</p> <p>1 MR. DAVIS: And please let me get</p> <p>2 some objections on the record.</p> <p>3 And I'm going to object to form on</p> <p>4 that.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: Okay.</p> <p>7 A. As I previously stated, a product can be</p> <p>8 considered to be adulterated if the CGMPs were not</p> <p>9 followed in the manufacturing of the product, even</p> <p>10 if there is nothing wrong with the product.</p> <p>11 Q. What is your basis for that statement?</p> <p>12 A. FDA states that in numerous places.</p> <p>13 Q. Okay. Can you identify one place where</p> <p>14 FDA states that?</p> <p>15 A. Okay. Well, one good example is</p> <p>16 virtually every single warning letter states in the</p> <p>17 warning letter, because CGMPs were not met, the</p> <p>18 product is considered to be adulterated.</p> <p>19 Any warning letter -- all the warning --</p> <p>20 we can pull up any of the warning letters we're</p> <p>21 talking about, and we would see that.</p> <p>22 Q. Any other basis for your statement with</p> <p>23 respect to CGMPs and adulteration?</p> <p>24 MR. DAVIS: Just for clarification</p> <p>25 for my purposes. I might be lost here. What's the</p>	<p style="text-align: right;">Page 97</p> <p>1 letter, and it would say that.</p> <p>2 The other point I would pull up here,</p> <p>3 which I state in my report relative to FDA's</p> <p>4 statement. This has to do with -- they say if --</p> <p>5 this is No. 34: FDA has formalized this in the</p> <p>6 active pharmaceutical ingredient (API) process</p> <p>7 inspection manual to further state "A firm is not in</p> <p>8 a sufficient state of control if any one system as</p> <p>9 defined in this program is found to be significantly</p> <p>10 noncompliant of CGMPs such that the quality,</p> <p>11 identity, and purity of the API resulting from that</p> <p>12 system cannot be adequately assured."</p> <p>13 Q. What paragraph in your report are you</p> <p>14 reading, sir?</p> <p>15 A. 34.</p> <p>16 (Reporter admonishment.)</p> <p>17 Q. You cite to some sources in that</p> <p>18 Paragraph 34 that you were reading from. Correct?</p> <p>19 MR. DAVIS: Excuse me, Counsel.</p> <p>20 Somebody was shuffling paper when you asked the</p> <p>21 question. It was inaudible on our end.</p> <p>22 MS. ISIDRO: That was the witness.</p> <p>23 Can we have that question read back,</p> <p>24 please?</p> <p>25 (The requested material was read.)</p>

25 (Pages 94 - 97)

<p style="text-align: right;">Page 98</p> <p>1 A. Correct.</p> <p>2 Q. Are those the sources from which you</p> <p>3 obtained the quotes that you have in Paragraph 34?</p> <p>4 A. The quote -- I'm not sure which one of</p> <p>5 those footnotes references where the quote came</p> <p>6 from. I'd have to go back and look at these</p> <p>7 specific ones, but it came from an FDA source.</p> <p>8 Q. One of the sources that you cite there is</p> <p>9 a 2005 PowerPoint presentation. Is that correct?</p> <p>10 A. That's correct. But the other one is the</p> <p>11 compliance program manual. That's the API</p> <p>12 Compliance Program Manual.</p> <p>13 Q. And the statement that you're -- which of</p> <p>14 the quotes are attributable to the program manual in</p> <p>15 Paragraph 34?</p> <p>16 MR. DAVIS: Do you want him to look</p> <p>17 at the program manual?</p> <p>18 MS. ISIDRO: Well, he's saying that</p> <p>19 that's where they came from, so I'm asking him to</p> <p>20 identify which ones came from that source.</p> <p>21 MR. DAVIS: Well, I think he said</p> <p>22 that some of them came from that source.</p> <p>23 A. If we could pull up the document, we</p> <p>24 could look at it, and I could show you.</p> <p>25 (Exhibit 9 was marked.)</p>	<p style="text-align: right;">Page 100</p> <p>1 Are you referring to the enumerated list</p> <p>2 on the bottom of Page 8 and the top of Page 9?</p> <p>3 A. I am. And if we go back -- if we go back</p> <p>4 to Page 7, and if we look at the second paragraph:</p> <p>5 A firm is not in a sufficient state of control if</p> <p>6 any one system as defined in this program is found</p> <p>7 to be significantly noncompliant with CGMPs, such</p> <p>8 that the quality, identity, and purity of the API</p> <p>9 resulting from the system cannot be adequately</p> <p>10 assured.</p> <p>11 Q. Now, that quote that you just read, that</p> <p>12 refers to significantly noncompliant with CGMPs.</p> <p>13 Correct?</p> <p>14 A. It says -- that's what it says.</p> <p>15 Q. It's not simply any noncompliance with</p> <p>16 CGMPs. Correct?</p> <p>17 A. It says -- it does say "significantly</p> <p>18 noncompliant."</p> <p>19 Q. So how does that statement provide a</p> <p>20 basis for your conclusion that any CGMP</p> <p>21 noncompliance causes all products from a particular</p> <p>22 facility to be considered adulterated?</p> <p>23 MR. DAVIS: Object to form,</p> <p>24 mischaracterizes his testimony.</p> <p>25 You can answer.</p>
<p style="text-align: right;">Page 99</p> <p>1 MS. ISIDRO: And we are marking as</p> <p>2 Exhibit 9 FDA Compliance Program Guidance Manual</p> <p>3 7356.002F.</p> <p>4 MR. DAVIS: Do you want to take a few</p> <p>5 minutes to review the document?</p> <p>6 THE WITNESS: Yes.</p> <p>7 A. (Pause.)</p> <p>8 So if we look at Page 8 and 9 in this</p> <p>9 document, it refers to the various systems on Page 8</p> <p>10 and 9.</p> <p>11 Q. Uh-huh.</p> <p>12 A. And if we go back to Page 7 --</p> <p>13 Q. Let me make sure I'm following you. So</p> <p>14 Page 8 and 9?</p> <p>15 A. Describes the systems.</p> <p>16 MR. DAVIS: Is there a question</p> <p>17 pending? You're not being asked to just describe</p> <p>18 the document. You're supposed to respond to</p> <p>19 questions.</p> <p>20 Q. You may continue.</p> <p>21 MR. DAVIS: Well, no, no. He has</p> <p>22 to -- he's only here to respond to your questions.</p> <p>23 Q. You started to say, "So if we look at</p> <p>24 Pages 8 and 9 in this document, it refers to the</p> <p>25 various systems."</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. And if I'm mischaracterizing your</p> <p>2 opinion, please feel free to correct me.</p> <p>3 A. So I'm reading here what this guidance</p> <p>4 document says. What I'm referring to in my report,</p> <p>5 relative to the class group that we're talking</p> <p>6 about, has to do with CGMPs.</p> <p>7 I'm just making the point here as to what</p> <p>8 FDA says about any one of the systems.</p> <p>9 Q. Okay.</p> <p>10 A. That was the -- put in the context of</p> <p>11 good manufacturing practices.</p> <p>12 Q. But you say in Paragraph 32 of your</p> <p>13 report that: FDA's official position regarding</p> <p>14 CGMPs is that if a company is not complying with</p> <p>15 CGMP regulations, any drug it makes is considered</p> <p>16 adulterated under the law.</p> <p>17 A. Right.</p> <p>18 Q. So where is your basis for that</p> <p>19 statement?</p> <p>20 A. So I go back to -- we can pull up --</p> <p>21 there is other guidance documents. I just probably</p> <p>22 didn't reference it here. You pull up any warning</p> <p>23 letter, we're talking about right in the body, the</p> <p>24 first body -- the first part of the warning letter,</p> <p>25 it will talk about the products that are considered</p>

<p style="text-align: right;">Page 102</p> <p>1 to be adulterated.</p> <p>2 MR. DAVIS: And, again, object to the</p> <p>3 form.</p> <p>4 Q. Do you have any support for that</p> <p>5 statement in Paragraph 32, other than the body of</p> <p>6 warning letters?</p> <p>7 MR. DAVIS: The footnote.</p> <p>8 MS. ISIDRO: I'm sorry. Are you</p> <p>9 testifying?</p> <p>10 MR. DAVIS: I mean, it's just</p> <p>11 obvious. He's cited it in his report.</p> <p>12 MS. ISIDRO: Are you testifying?</p> <p>13 MR. DAVIS: Okay. You can answer the</p> <p>14 question.</p> <p>15 A. I think it's -- I think it's actually --</p> <p>16 let's see here. Yes, it's Footnote 8. So if we can</p> <p>17 pull up Footnote 8 --</p> <p>18 Q. Okay.</p> <p>19 A. -- that document.</p> <p>20 UNIDENTIFIED SPEAKER: Which document</p> <p>21 are you referring to?</p> <p>22 MR. DAVIS: It's not been marked as</p> <p>23 an exhibit yet.</p> <p>24 Q. Let's mark this as Exhibit 10.</p> <p>25 MR. DAVIS: 10.</p>	<p style="text-align: right;">Page 104</p> <p>1 adulterated. Correct?</p> <p>2 A. No --</p> <p>3 MR. DAVIS: Object to form.</p> <p>4 A. -- that's not correct.</p> <p>5 THE WITNESS: I'm sorry.</p> <p>6 MR. DAVIS: Sorry.</p> <p>7 A. That's not correct.</p> <p>8 Q. Is it your opinion that a single minor</p> <p>9 observation about a single product line in a 483</p> <p>10 represents the FDA's determination that all products</p> <p>11 manufactured at that facility are adulterated?</p> <p>12 MR. DAVIS: Objection; improper</p> <p>13 hypothetical.</p> <p>14 You can answer.</p> <p>15 A. That's not what I've stated. What I'm</p> <p>16 stating is what FDA has stated. Okay? And I'll say</p> <p>17 it again.</p> <p>18 If a company is not complying with CGMP</p> <p>19 regulations, any drug it makes is considered</p> <p>20 adulterated under the law. That's what the FDA</p> <p>21 states. That's not what John Quick states. That's</p> <p>22 what the FDA states.</p> <p>23 Q. And, again, those would have to be</p> <p>24 significant CGMP violations, significant enough to</p> <p>25 rise to that level. Correct?</p>
<p style="text-align: right;">Page 103</p> <p>1 (Exhibit 10 was marked.)</p> <p>2 Q. Okay. I am handing you what's been</p> <p>3 marked as Exhibit 10. Is this the document that's</p> <p>4 cited in Footnote 8?</p> <p>5 A. It is.</p> <p>6 Q. Okay. Now, can you show me --</p> <p>7 A. Sure. Go to Page 2.</p> <p>8 Q. Okay.</p> <p>9 A. The last section in that page, the second</p> <p>10 paragraph from the bottom.</p> <p>11 It says: If a company is not complying</p> <p>12 with CGMP regulations, any drug it makes is</p> <p>13 considered adulterated under the law. This kind of</p> <p>14 adulteration means that the drug was not</p> <p>15 manufactured under conditions that comply with CGMP.</p> <p>16 It does not mean that there is necessarily anything</p> <p>17 wrong with the drug.</p> <p>18 Q. And that applies with respect to any drug</p> <p>19 for which the CGMP regulations were not followed.</p> <p>20 Correct?</p> <p>21 A. No, that's not correct. That's not what</p> <p>22 I said. That's not what this says. You said</p> <p>23 something different.</p> <p>24 Q. So any CGMP observation with respect to</p> <p>25 any system does not automatically render a product</p>	<p style="text-align: right;">Page 105</p> <p>1 A. It doesn't say that. It doesn't say that</p> <p>2 here.</p> <p>3 Q. Okay.</p> <p>4 A. Okay.</p> <p>5 Q. But the other document we looked at does.</p> <p>6 Correct?</p> <p>7 A. That was the document for Q7. They're</p> <p>8 different documents.</p> <p>9 Q. Right. But the other document did say</p> <p>10 that. Correct?</p> <p>11 MR. DAVIS: For the record, are you</p> <p>12 referring to Exhibit 9?</p> <p>13 Q. The FDA compliance program manual?</p> <p>14 A. Right.</p> <p>15 Q. Exhibit 9. Correct?</p> <p>16 A. No, Exhibit 11. I think it's Exhibit --</p> <p>17 no. Yeah, it is. It's Exhibit 9 and 11.</p> <p>18 MR. DAVIS: You're referring -- just</p> <p>19 for clarification, I believe the witness is</p> <p>20 referring to Footnote 11, which is marked as</p> <p>21 Exhibit 9.</p> <p>22 Q. The FDA compliance program manual,</p> <p>23 7356.002F. Correct?</p> <p>24 A. Right.</p> <p>25 Q. To determine if a product is adulterated</p>

<p style="text-align: right;">Page 106</p> <p>1 due to CGMP violations, you would need to look at 2 the specific violations. Correct? 3 A. Well, again, I'll go back to what it says 4 here. It doesn't say that, okay, in terms of that. 5 So it doesn't say whether it's a minor thing or 6 major. It doesn't say that here. Okay? 7 But -- and the situation we're talking 8 about here, for the companies we're talking about -- 9 and eventually we're probably going to get into 10 that -- is that there were a number of situations, a 11 number of examples I had here where there were CGMP 12 violations. 13 And, again, those are the things that the 14 FDA refers to as being adulterated. I was trying to 15 put it into the context of what you asked relative 16 to where the reference was with the FDA. 17 Q. So, again, I just want to make sure that 18 I understand what your position is. 19 Is it your position that any individual 20 CGMP violation renders each and every product that 21 is manufactured at that facility where that CGMP 22 violation occurred adulterated? 23 MR. DAVIS: Objection to form; 24 mischaracterizes his testimony so far in his report. 25 A. That's not what my report --</p>	<p style="text-align: right;">Page 108</p> <p>1 companies relative to the class group, okay, in 2 regard to these various companies. And I'm pointing 3 out the FDA's interpretation of that is you have the 4 CGMP violations, the products are considered to be 5 adulterated. 6 I didn't say that the FDA says that for 7 CGMP -- CGMP violations. I'm not saying that these 8 products are adulterated. I'm saying that they 9 violated -- that they were not in compliance with 10 CGMPs. 11 Q. So you're not saying that any 12 valsartan-containing drug was adulterated? 13 A. No, I do not. 14 MR. DAVIS: Objection. 15 THE WITNESS: Sorry. 16 MR. DAVIS: And mischaracterizes his 17 report. 18 A. I didn't say that. 19 (Discussion off the written record.) 20 (The requested material was read.) 21 Q. I just want to make sure -- withdrawn. 22 So just to clarify, are you stating that 23 it is the FDA's position that a single minor 24 observation about a single product line in a 483 25 represents FDA's determination that all products</p>
<p style="text-align: right;">Page 107</p> <p>1 (Simultaneous speaking.) 2 MR. DAVIS: You can answer. 3 THE WITNESS: I'm sorry. 4 MR. DAVIS: Wait for me to finish my 5 instruction. 6 Mischaracterizes his testimony and 7 his report. 8 You can answer. 9 A. So that's not what my report says. My 10 report basically says that I'm referring to the 11 CG -- you're putting your hand up. 12 My report says that I'm referring to the 13 CGMP violations of the company relative to the class 14 group. That's what I'm referring to. I don't get 15 into the fact that those are adulterated. I don't 16 say that. I'm just talking about the violations as 17 they apply to the class group. I'm just referring 18 to what the FDA refers to -- as to these as, as 19 being adulterated. 20 Q. So you're not rendering an opinion as to 21 any -- as to whether any product was adulterated? 22 MR. DAVIS: Objection to form; 23 mischaracterizes his testimony and his report. 24 A. So I'll say again what I just said, is 25 I'm referring to the GMP violations of the various</p>	<p style="text-align: right;">Page 109</p> <p>1 manufactured at that facility are adulterated? 2 MR. DAVIS: Counsel, I'm going to 3 go -- you're reading the exact same question you 4 read two minutes ago. It's asked and answered. 5 You can answer it one more time, 6 Mr. Quick. 7 A. Okay. So I'm not going to characterize 8 the FDA's interpretation of anything. I'm just 9 telling you what the FDA says about CGMP violations. 10 You're imposing a specific situation, which is not 11 what FDA -- that's not what the FDA says here. I'm 12 just telling you what the FDA does say about CGMP 13 violations relative to adulteration. 14 You're asking a question that's not posed 15 there. 16 Q. Did you review specific CGMP violations 17 here? 18 A. "Here" what? 19 Q. In connection with this litigation. 20 A. I'm sorry. In conjunction with what? 21 Q. In connection with this litigation. 22 A. Yes. 23 THE VIDEOGRAPHER: I need to start a 24 new file. Can we take a break? 25 MS. ISIDRO: Yes, we can take a</p>

<p style="text-align: right;">Page 110</p> <p>1 break.</p> <p>2 THE VIDEOGRAPHER: Off the record,</p> <p>3 12:38 p.m.</p> <p>4 (Break.)</p> <p>5 THE VIDEOGRAPHER: We are back on the</p> <p>6 record at 1:27 p.m. This marks the beginning of</p> <p>7 Media Unit 2.</p> <p>8 Q. All right. Mr. Quick, you still have</p> <p>9 Exhibit 6 in front of you, which is your report in</p> <p>10 this litigation. Correct?</p> <p>11 A. Right.</p> <p>12 Q. Is it fair to say that roughly the first</p> <p>13 half of your report, through Paragraph 100 on</p> <p>14 Page 20, is it fair to say that that portion of your</p> <p>15 report recounts your understanding of the FDA's</p> <p>16 regulatory policies and procedures?</p> <p>17 MR. DAVIS: Object to form.</p> <p>18 You can answer.</p> <p>19 A. Yes, I believe that to be the case.</p> <p>20 Q. Okay. And then the remainder of your</p> <p>21 report addresses specific issues with various</p> <p>22 defendants in the present litigation. Correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Now, we've talked about Exhibit A</p> <p>25 to your report.</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. Okay. Now, on Exhibit A, the materials</p> <p>2 relied upon for your declaration, there are a number</p> <p>3 of documents that were produced by the defendants in</p> <p>4 this action. Correct?</p> <p>5 A. That -- that is right. Yes.</p> <p>6 Q. But these are not all of the documents</p> <p>7 that were produced by the defendants in this action.</p> <p>8 Correct?</p> <p>9 A. That is right, yes.</p> <p>10 Q. Okay. And how did you determine which</p> <p>11 documents would be listed on your reliance list and</p> <p>12 which ones would not?</p> <p>13 MR. DAVIS: Object to form.</p> <p>14 A. Well, there was no specific conscious</p> <p>15 determination as to which ones. I went through the</p> <p>16 various GMP issues and I used the documents to refer</p> <p>17 to those as part of the documents that I relied on.</p> <p>18 And, again, the point -- like I said this</p> <p>19 morning, these are just examples.</p> <p>20 Q. When you say "these are just examples,"</p> <p>21 what are you --</p> <p>22 A. The C --</p> <p>23 Q. -- referring to?</p> <p>24 A. The CGMP issues.</p> <p>25 Q. And you're referring now to the</p>
<p style="text-align: right;">Page 111</p> <p>1 A. Which exhibit?</p> <p>2 Q. Exhibit A to your report, the materials</p> <p>3 relied upon for your declaration.</p> <p>4 Did you put this list together yourself?</p> <p>5 A. Well, I -- I believe that this list</p> <p>6 represents the footnotes that I used -- referenced</p> <p>7 in the report. It's a summary of that. I didn't</p> <p>8 specifically put this compilation together. I think</p> <p>9 those -- that was a compilation of what was in the</p> <p>10 footnotes.</p> <p>11 Q. So who created that compilation for you?</p> <p>12 A. I think it would have been the law firm.</p> <p>13 Q. And what about the report itself, did you</p> <p>14 draft the report itself?</p> <p>15 A. Yes.</p> <p>16 Q. On your own?</p> <p>17 A. Yes. Let me, I'll clarify, there was</p> <p>18 some formatting things that -- and the group</p> <p>19 reviewed it, there was some formatting points that</p> <p>20 they made in the -- in the report.</p> <p>21 Q. But as far as putting pen to paper or</p> <p>22 keys to keyboard --</p> <p>23 A. It was my --</p> <p>24 Q. -- that was you?</p> <p>25 A. I did.</p>	<p style="text-align: right;">Page 113</p> <p>1 discussion after Paragraph 100 of your report?</p> <p>2 A. Yes.</p> <p>3 Q. Paragraphs 101 through 191 of your</p> <p>4 report?</p> <p>5 A. Yes.</p> <p>6 Q. And you testified earlier that everything</p> <p>7 that you relied on is either in the Exhibit A to</p> <p>8 your report or in the footnotes to your report.</p> <p>9 Correct?</p> <p>10 A. Yes.</p> <p>11 (Discussion off the written record.)</p> <p>12 Q. Before marketing a new drug, the</p> <p>13 manufacturer's sponsor has to submit a new drug</p> <p>14 application to the FDA. Correct?</p> <p>15 A. Or an abbreviated new drug application.</p> <p>16 Q. Okay. But this is for a new drug?</p> <p>17 A. Oh, new drug, yes. New drug.</p> <p>18 Q. So new drug, new drug application.</p> <p>19 Correct?</p> <p>20 A. That is right.</p> <p>21 Q. Okay. And the new drug application has</p> <p>22 to demonstrate that the medication meets statutory</p> <p>23 standards for safety and effectiveness. Correct?</p> <p>24 A. Yes.</p> <p>25 Q. And it also has to establish that it</p>

<p style="text-align: right;">Page 114</p> <p>1 meets manufacturing and controls and labeling and so 2 forth? 3 A. There are a number of things, among other 4 things, yes. 5 Q. And the FDA has to grant its approval to 6 that new drug application before the new drug 7 product can be marketed. Right? 8 A. Yes. The FDA has to approve the 9 application, yes. 10 Q. Okay. And a manufacturer of a generic 11 drug must submit an abbreviated new drug 12 application. Correct? 13 A. There -- there's some other 14 possibilities, but typically it would be an 15 abbreviated new drug application. 16 Q. Okay. And what are the other 17 possibilities you're -- 18 A. Well, I think that's a 5 -- 19 Q. -- referring to? 20 A. I think it's 5 -- 503, 505(b)(3) or 21 something like that. But typically, it'd be an 22 ANDA. 23 Q. And the generic drug can only be marketed 24 after the FDA approves that application. Correct? 25 A. That's right.</p>	<p style="text-align: right;">Page 116</p> <p>1 ingredient. 2 Q. Have you reviewed the ANDA for any 3 valsartan-containing drug products? 4 A. I don't believe so. 5 Q. Have you reviewed any of the 6 bioequivalence data associated with any of the ANDAs 7 for valsartan or valsartan-containing products? 8 A. I don't believe so. That was -- that was 9 not within the scope of what I was looking at. 10 Q. Okay. When a drug comes to market via 11 the ANDA process, the ANDA applicant typically 12 doesn't have to con -- to conduct or include 13 additional preclinical or clinical safety and 14 efficacy trials. Correct? 15 A. They could. I'm not -- I'm not opining 16 on what -- what they may or may not have to do. FDA 17 will ask questions when they're going through the 18 review process and -- so I'm not going to say there 19 would not be that possibility. 20 Q. But under the -- the ANDA process, 21 generics are typically granted approval status based 22 on the safety and efficacy data that was previously 23 submitted by the drug innovator or the ANDA holder. 24 Right? 25 A. That's my understanding, but that's not</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. In order to obtain approval of an ANDA, 2 an applicant has to include, among many other 3 things, information to show that the drug is 4 bioequivalence to the reference listed drug. 5 Correct? 6 A. Well, they've got to show it's 7 therapeutic equivalent and bioequivalence is part of 8 that. 9 Q. So bioequivalence is one of the things -- 10 A. Right. 11 Q. -- they have to show. Right? 12 A. Yes. 13 Q. Okay. And I'll just remind you, I know 14 we just came back from the lunch break, but I'll 15 just remind you to please wait until I finish my 16 question before starting your answer just so that 17 the court reporter can make sure that everything is 18 recorded accurately on the record. Thank you. 19 And an ANDA applicant also has to include 20 information showing that the active ingredients of 21 the proposed generic drug are of the same 22 pharmaceutical or therapeutic class as those in the 23 RLD. Right? 24 A. Well, they have to show that they contain 25 identical amounts to the identical active drug</p>	<p style="text-align: right;">Page 117</p> <p>1 what I'm opining on, though. 2 Q. Okay. Are you aware of how FDA defines 3 active ingredient? 4 A. Active ingredient is the ingredient 5 that's intended to treat the patient as opposed to 6 an inactive ingredient. 7 Q. Would any component that provides 8 pharmacologic -- 9 MS. ISIDRO: I'll withdraw that 10 question. Let's pause for a moment. Just go off 11 the record for a moment. 12 THE VIDEOGRAPHER: Off the record, 13 1:37 p.m. 14 (Break.) 15 THE VIDEOGRAPHER: Back on the 16 record, 1:39 p.m. 17 Q. Would you agree that any component that 18 provides pharmacologic activity or other direct 19 effects in the diagnosis, cure or mitigation, 20 treatment or prevention of disease or to affect the 21 structure or any function of the body, would qualify 22 as an active ingredient? 23 MR. DAVIS: Objection. 24 You can answer. 25 A. That sounds reasonable, but that's not</p>

<p style="text-align: right;">Page 118</p> <p>1 what I'm opining on.</p> <p>2 Q. Okay. And while an ANDA approved drug</p> <p>3 will have the same active ingredient as the</p> <p>4 reference listed drug, it may contain different</p> <p>5 inactive ingredients as long as they don't interfere</p> <p>6 with achieving bioequivalence of the active</p> <p>7 ingredient --</p> <p>8 MR. DAVIS: Objection.</p> <p>9 Q. -- right?</p> <p>10 MR. DAVIS: Object to form, and</p> <p>11 misrepresents the -- the law.</p> <p>12 You can answer.</p> <p>13 A. So it -- it probably depends upon what it</p> <p>14 is in terms of the application process. The FDA may</p> <p>15 object to something. I don't know. It -- we're</p> <p>16 trying to generalize something that might</p> <p>17 be specific to a very individual drug.</p> <p>18 Q. Would you agree that FDA does not require</p> <p>19 the inactive ingredients of an ANDA approved drug to</p> <p>20 be identical to the inactive ingredients of an NDA</p> <p>21 approved drug?</p> <p>22 A. I believe that to be correct but, again,</p> <p>23 that's not what I'm opining on.</p> <p>24 Q. Would you agree that each manufacturer of</p> <p>25 valsartan in this litigation had to submit their own</p>	<p style="text-align: right;">Page 120</p> <p>1 ten minutes has been, "this is outside the scope."</p> <p>2 So I'd say move on if it's not in his report.</p> <p>3 Q. Do you remember the question or did we --</p> <p>4 A. I do --</p> <p>5 Q. -- need to have it read back?</p> <p>6 A. I do remember the question. Again --</p> <p>7 again, I'm not opining on that. FDA could come back</p> <p>8 and ask for something else as part of the</p> <p>9 application review process, so I don't know.</p> <p>10 Q. But you would agree that each ANDA</p> <p>11 applicant has to submit its own bioequivalence</p> <p>12 studies?</p> <p>13 MR. DAVIS: Objection; asked and</p> <p>14 answered and he said it's outside the scope.</p> <p>15 You can answer one more time.</p> <p>16 A. So, as I said, it's not something I'm</p> <p>17 opining on. The FDA, when you make a submission to</p> <p>18 the FDA, they can come back and ask for additional</p> <p>19 information. So I -- it's possible they could ask</p> <p>20 for something else. I don't know.</p> <p>21 Q. I understand you're referring to what FDA</p> <p>22 may or may not ask to in follow-up. But in</p> <p>23 submitting an ANDA initially, the respective</p> <p>24 applicant has to submit bioequivalence studies in</p> <p>25 support of that ANDA. Right?</p>
<p style="text-align: right;">Page 119</p> <p>1 ANDA for -- for their generic products?</p> <p>2 A. So there must be something else that</p> <p>3 you're trying to get to here, but I -- I'm not sure</p> <p>4 why you would ask that question. I mean, obviously</p> <p>5 if you want to get approval, you've got to submit</p> <p>6 your ANDA to the FDA to get approval.</p> <p>7 Q. So it's not important why I'm asking the</p> <p>8 question, I just need you to answer the question</p> <p>9 that was asked.</p> <p>10 A. Well, I mean, it sounds reasonable what</p> <p>11 you're saying, but I may not be understanding fully</p> <p>12 what you're asking.</p> <p>13 Q. You would agree that each separate</p> <p>14 manufacturer of a generic drug, including valsartan,</p> <p>15 has to submit its own ANDA for approval of its</p> <p>16 particular product. Correct?</p> <p>17 A. That would sound to be reasonable.</p> <p>18 Q. Okay. And each manufacturer would have</p> <p>19 to submit its own bioequivalence studies in support</p> <p>20 of its respective ANDA. Correct?</p> <p>21 MR. DAVIS: I'm going to object to.</p> <p>22 This -- this is outside the scope. He's says he's</p> <p>23 not opining on bioequivalence data or he hasn't</p> <p>24 looked at that, it's not part of his report. I</p> <p>25 mean, every single answer he's given for the last</p>	<p style="text-align: right;">Page 121</p> <p>1 A. That sounds re- --</p> <p>2 MR. DAVIS: Same objections.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: Okay.</p> <p>5 A. That sounds reasonable. Again, that's</p> <p>6 outside the scope of what I've looked at.</p> <p>7 Q. All right. Let's take a look at</p> <p>8 Paragraph 16 of your report.</p> <p>9 A. Okay.</p> <p>10 Q. In this paragraph, which does have cer --</p> <p>11 a number of subparagraphs, in this paragraph you</p> <p>12 refer to FDA reviewers. Correct?</p> <p>13 A. I'm referring to the FDA fact sheet,</p> <p>14 which is where that information came from.</p> <p>15 Q. But you do make reference in several</p> <p>16 places to FDA reviewers. Correct?</p> <p>17 A. Well, let's see. I need to take a look</p> <p>18 at this.</p> <p>19 Q. Just one example, if you look at</p> <p>20 Paragraph -- at Subparagraph C, about halfway down,</p> <p>21 there is a sentence starting with "FDA reviewers</p> <p>22 will study."</p> <p>23 A. B? You're referring to B?</p> <p>24 Q. No, C as in Charlie.</p> <p>25 A. Oh, C. Okay.</p>

<p style="text-align: right;">Page 122</p> <p>1 It does say, yes, FDA reviewers.</p> <p>2 Q. Okay. And so when you refer to "FDA</p> <p>3 reviewers" in your report, is that what's also known</p> <p>4 as review chemists?</p> <p>5 A. So, as I said before, what I'm</p> <p>6 referencing here is what FDA states in their fact</p> <p>7 sheet. Okay? That's -- I mean I'm just</p> <p>8 paraphrasing what FDA says. It could involve</p> <p>9 chemists.</p> <p>10 Q. Okay. But --</p> <p>11 A. It could involve others.</p> <p>12 Q. You're stating this in your report, and I</p> <p>13 just want to get your understanding as to whether</p> <p>14 the term "FDA reviewers," as it appears there in</p> <p>15 Paragraph 16(c), whether that is what is also known</p> <p>16 as a review chemists.</p> <p>17 MR. DAVIS: Objection; asked and</p> <p>18 answered. He has provided his understanding. He</p> <p>19 said "Could be chemists. Could be others." He</p> <p>20 answered it.</p> <p>21 A. So I'll say the same thing again. It</p> <p>22 could include chemists. It could include others.</p> <p>23 It probably depends upon the application. It</p> <p>24 probably depends on who they want to have take a</p> <p>25 look at the particular file.</p>	<p style="text-align: right;">Page 124</p> <p>1 A. They will ask -- they will ask the</p> <p>2 office, "Is the firm in compliance" -- they'll ask</p> <p>3 three things, is the firm in compliance, have they</p> <p>4 had a recent inspection, does the firm require a</p> <p>5 preapproval inspection, or is the firm out of</p> <p>6 compliance?</p> <p>7 And so, depending on what the answer is,</p> <p>8 that will be their action. If they have recently</p> <p>9 had an inspection that was a good inspection, they</p> <p>10 may not ask for a new preapproval inspection, they</p> <p>11 may rely on the old one.</p> <p>12 If -- most likely, they will have a</p> <p>13 preapproval inspection. Or, if there is something</p> <p>14 out of compliance, they will say, "No, this should</p> <p>15 not be approved."</p> <p>16 It depends upon the individual</p> <p>17 circumstance.</p> <p>18 And if you notice, in a lot of the</p> <p>19 warning letters, the FDA makes the statement, future</p> <p>20 submissions will not -- basically, will not be</p> <p>21 approved, until the warning letter is resolved.</p> <p>22 Q. Are you familiar with FDA's district</p> <p>23 laboratories?</p> <p>24 A. I know they have laboratories. Okay?</p> <p>25 Have I been to one of the FDA district laboratories?</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Does your term "FDA reviewers" include</p> <p>2 inspectors?</p> <p>3 A. In the context here, this is referring to</p> <p>4 the FDA review process, which would typically not</p> <p>5 include -- and they -- I refer to "investigators."</p> <p>6 The FDA -- I wouldn't use the term "inspectors" with</p> <p>7 the FDA anyway. They're FDA investigators. This</p> <p>8 would not include that term.</p> <p>9 Q. Okay.</p> <p>10 A. You would never refer to an FDA</p> <p>11 investigator as an inspector.</p> <p>12 Q. Okay. And reviewers would not actually</p> <p>13 accompany investigators in the field. Correct?</p> <p>14 A. Not always. I think -- believe sometimes</p> <p>15 they have. That's -- that would not be typical.</p> <p>16 Q. Okay. Reviewers will send requests to</p> <p>17 the Office of Regulatory Affairs at the time that an</p> <p>18 application is nearing approval. Right?</p> <p>19 A. That's right.</p> <p>20 Q. And that could be to arrange for CGMP</p> <p>21 compliance inspection of the applicant's</p> <p>22 manufacturing facilities?</p> <p>23 A. So here is how this process works. It's</p> <p>24 not quite the way you described it.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 125</p> <p>1 No, I've not.</p> <p>2 Q. And do those FDA district laboratories</p> <p>3 participate in essentially verifying that the</p> <p>4 information submitted to the FDA is accurate?</p> <p>5 MR. DAVIS: Objection; vague.</p> <p>6 You can answer.</p> <p>7 A. So I'm not certain exactly what these</p> <p>8 laboratories would do in this review process. They</p> <p>9 may or may not do something. I don't know. They</p> <p>10 may not even choose to use these laboratories. I</p> <p>11 don't know. Probably depends upon the individual</p> <p>12 application.</p> <p>13 Q. And would the activities of the FDA's</p> <p>14 district laboratories be outside the scope of your</p> <p>15 opinions, in your view?</p> <p>16 A. Well, it is outside the scope, because</p> <p>17 I've not referenced them.</p> <p>18 Q. And you're not going to be offering any</p> <p>19 opinions in this litigation that are outside the</p> <p>20 scope of your report. Right?</p> <p>21 MR. DAVIS: Well, hang on. He has</p> <p>22 submitted this Declaration For a Class</p> <p>23 Certification. You said "this litigation." He may</p> <p>24 very well offer another expert report in this</p> <p>25 litigation, so I want to make that very clear.</p>

<p style="text-align: right;">Page 126</p> <p>1 But, with that, you can answer.</p> <p>2 THE WITNESS: Sure.</p> <p>3 A. This is not a merits report. This is a</p> <p>4 declaration. So if I -- if there is additional</p> <p>5 reports, it may well extend beyond this.</p> <p>6 Q. Are you intending to offer any opinions</p> <p>7 in this litigation with respect to the activities of</p> <p>8 district laboratories, FDA district laboratories?</p> <p>9 A. Not as it pertains to this declaration.</p> <p>10 Q. Are you going to opine in this litigation</p> <p>11 on the content of the ANDAs for valsartan or</p> <p>12 valsartan-containing products?</p> <p>13 MR. DAVIS: Objection; calls for</p> <p>14 speculation. I'm not even sure how he can answer a</p> <p>15 question like that.</p> <p>16 A. So I've not been asked to do anything</p> <p>17 beyond this declaration at this point in time, so</p> <p>18 the answer is I don't know.</p> <p>19 Q. Are you going to offer any opinions with</p> <p>20 respect to what is required to be in ANDA?</p> <p>21 MR. DAVIS: Same objection. And,</p> <p>22 again, another objection on this is that we're not</p> <p>23 required to disclose merits experts yet. So if</p> <p>24 that's what you're trying to do, is to get him to</p> <p>25 disclose himself as a merits expert, I object to</p>	<p style="text-align: right;">Page 128</p> <p>1 what, I'm going to withdraw the instruction, because</p> <p>2 I don't see what he could possibly say. Because he</p> <p>3 has no idea what -- he hasn't been asked to do</p> <p>4 anything like that, and it's -- this would call for</p> <p>5 pure and utter speculation on his part.</p> <p>6 So I don't see where you're going</p> <p>7 with this question. I think it's an utter waste of</p> <p>8 time. You've asked the same question five times in</p> <p>9 a row now. His answer is going to be the same.</p> <p>10 But you can answer one more time.</p> <p>11 MS. ISIDRO: The record is clear that</p> <p>12 I have not asked the same question five times in a</p> <p>13 row.</p> <p>14 And he has offered testimony that</p> <p>15 there are certain things that are beyond the scope</p> <p>16 of his opinions, and so we need to confirm that he</p> <p>17 won't be opining beyond the opinions that he has</p> <p>18 identified here today, absent proper disclosure in</p> <p>19 the litigation.</p> <p>20 MR. DAVIS: But your question is</p> <p>21 whether he's going to do so in this litigation, and</p> <p>22 that's what I'm objecting to. So if you want to</p> <p>23 rephrase your question, you can rephrase it.</p> <p>24 But as far as whether he's going to</p> <p>25 at some point in the future render a merits expert</p>
<p style="text-align: right;">Page 127</p> <p>1 that, and I would probably instruct him not to</p> <p>2 answer.</p> <p>3 I don't think -- I don't see where</p> <p>4 you're going with asking about what he might</p> <p>5 hypothetically do in the future if we ask him. He</p> <p>6 doesn't know that.</p> <p>7 Q. In connection -- withdrawn.</p> <p>8 Are you going to offer any opinions with</p> <p>9 respect to whether the impurity profile of an ANDA</p> <p>10 drug has to be exactly the same as the impurity</p> <p>11 profile for a reference listed drug?</p> <p>12 MR. DAVIS: Same objection.</p> <p>13 And I think I'm going to instruct the</p> <p>14 witness not to answer it.</p> <p>15 You're asking whether he might submit</p> <p>16 a report in the future that addresses something</p> <p>17 else, and we're not required to disclose experts yet</p> <p>18 on that. So, with that, I will -- I think I'm going</p> <p>19 to make an instruction.</p> <p>20 So you don't have to answer that.</p> <p>21 MS. ISIDRO: So --</p> <p>22 MR. KERNER: You're instructing the</p> <p>23 witness, who is not your client, not to answer a</p> <p>24 question?</p> <p>25 MR. DAVIS: Look, I mean, you know</p>	<p style="text-align: right;">Page 129</p> <p>1 report that may address some or all of those topics</p> <p>2 or none of them, you know, that calls for wild</p> <p>3 speculation, and he has no idea of how to answer</p> <p>4 that. And we're not required to disclose our</p> <p>5 experts on that point.</p> <p>6 MS. ISIDRO: Can we just read back</p> <p>7 the last question that was asked, and if there was</p> <p>8 any answer to it, let's get that answer read back.</p> <p>9 MR. DAVIS: I'm going to make an</p> <p>10 attorney-work-product objection as well to all those</p> <p>11 prior questions.</p> <p>12 (The requested material was read.)</p> <p>13 A. So the answer, again, as I said before,</p> <p>14 is I don't know. I've not been asked to do anything</p> <p>15 beyond this declaration document that you have, so I</p> <p>16 don't know.</p> <p>17 Q. Let's take a look at Paragraph 23 of your</p> <p>18 report.</p> <p>19 A. Which one?</p> <p>20 Q. Paragraph 23. And there is a reference</p> <p>21 about halfway through the paragraph, where you say:</p> <p>22 It is obvious that the regulations also take a much</p> <p>23 broader approach to their view of adulteration,</p> <p>24 including a manufacturer's compliance with CGMP,</p> <p>25 which might prevent products from becoming</p>

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1 contaminated in the first instance.
 2 Can you explain what you mean by "much
 3 broader approach to their view of adulteration"?
 4 A. Well, the point I made earlier relative
 5 to adulterated product is the fact that CGMPs are
 6 not being met, the product would be considered to be
 7 adulterated.
 8 If there was an example of adulteration
 9 of the other sort from a contamination standpoint,
 10 there might be a more in-depth review of CGMPs.
 11 Q. And did this broader approach that you
 12 reference impact your opinion with respect to
 13 whether the presence of NDMA or NDEA in defendants'
 14 valsartan adulterated the valsartan products?
 15 MR. DAVIS: Object to form.
 16 A. So my opinions were based on the CGMPs
 17 that I've observed through the review of the
 18 documents.
 19 Q. And when you say "through your review of
 20 the documents," are you referring to the documents
 21 that are listed on Exhibit A to your report?
 22 A. I am.
 23 Q. Okay. Is it your opinion that even a
 24 particular lot of valsartan that did not contain any
 25 detectable NDMA or NDEA was adulterated?

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1 MR. DAVIS: Objection; incomplete
 2 hypothetical.
 3 You can answer.
 4 A. So what I said before is that the product
 5 doesn't necessarily need to be adulterated to be
 6 considered to be adulterated -- I mean, contaminated
 7 to be considered adulterated if it's in violation of
 8 CGMPs.
 9 If it's in violation of CGMPs, the
 10 products are considered to be adulterated.
 11 Q. And when you say "if its in violation of
 12 CGMPs," does that "it" refer to the product?
 13 A. It refers to the way -- the quality
 14 systems in the last spec in terms of CGMPs which
 15 involve a number of different things.
 16 But if the firm is in violation of CGMPs,
 17 everything that they're making would be considered
 18 to be adulterated.
 19 I think we went through that this
 20 morning.
 21 Q. So to be clear, is it your opinion that
 22 if there was any CGMP violation anywhere in the
 23 firm, a particular lot of valsartan coming from that
 24 firm would be considered adulterated, even if it
 25 contained no detectable nitrosamines whatsoever?

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1 MR. DAVIS: Objection; incomplete
 2 hypothetical, asked and answered many times this
 3 morning.
 4 You can answer again.
 5 A. So I'll restate again what I said before,
 6 is that the position of the FDA is if the firm is
 7 not operating according to the CGMPs, the products
 8 that it's producing are considered to be
 9 adulterated, regardless as to whether they're
 10 contaminated or not.
 11 Q. So I understand that your answer refers
 12 to the position of FDA. You're not here speaking
 13 for FDA today. Correct?
 14 MR. DAVIS: He is speaking here about
 15 his interpretation of the FDA's regulations.
 16 Q. My question was you're not here speaking
 17 for FDA today. Correct?
 18 A. Of course I'm not here to speak for FDA.
 19 Q. I didn't think it was a controversial
 20 question.
 21 And my question to you for that reason
 22 was not what FDA's position is. My question to you
 23 was what is your opinion.
 24 Is it your opinion that if a firm had a
 25 CGMP violation anywhere in the firm, even if it was

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1 completely unrelated to valsartan, a particular lot
 2 of valsartan coming from that firm would be
 3 considered adulterated even if it contained no
 4 detectable nitrosamines whatsoever?
 5 MR. DAVIS: Objection; asked and
 6 answered again. Objection; incomplete hypothetical.
 7 Objection; relevance.
 8 You can answer.
 9 A. So I've answered your question before,
 10 but I'll answer it again. Okay?
 11 As I said before, if the CGMPs are not
 12 being met, the products that are being produced,
 13 regardless of whether there is contamination or not,
 14 are considered to be adulterated.
 15 Q. And that's your opinion?
 16 A. Well -- so I base opinions on what the
 17 regulatory requirements are. I don't -- I don't --
 18 as John Quick I don't dream up new regulations or
 19 new guidance. I don't do that. I follow what FDA
 20 says is the guidance and the regulation.
 21 Q. And so I'll ask again, is that your
 22 opinion?
 23 MR. DAVIS: Hang on. All these --
 24 I'm restating all my objections, and he's clarified
 25 what his opinion is. Asked and answered again.

<p style="text-align: right;">Page 134</p> <p>1 Like what else do you want to hear?</p> <p>2 A. What do you want -- what do you want to</p> <p>3 ask -- what do you want to hear again?</p> <p>4 Q. Let's look at Paragraph 25 of your</p> <p>5 report, starting with the second sentence in that</p> <p>6 paragraph.</p> <p>7 You state: For a facility to be in</p> <p>8 compliance with CGMP -- or, actually, let me</p> <p>9 rephrase that.</p> <p>10 So looking at Paragraph 25, you have</p> <p>11 quotation marks around the bulk of the language in</p> <p>12 Paragraph 25. Correct?</p> <p>13 A. I do, yes.</p> <p>14 Q. And you don't have a specific citation</p> <p>15 going with those quotation marks, do you?</p> <p>16 A. There is no footnote there.</p> <p>17 Q. Okay. You attribute this language</p> <p>18 generally to the FD&C Act, but you don't specify</p> <p>19 where in the FD&C Act it comes from?</p> <p>20 A. So it's probably one of the guidance</p> <p>21 documents like we reviewed this morning where that</p> <p>22 quote came. This is not a quote that I put</p> <p>23 together. It's a quote from the FDA, so -- or</p> <p>24 the -- or the act, so I'm not certain where that</p> <p>25 came from.</p>	<p style="text-align: right;">Page 136</p> <p>1 I'll say okay.</p> <p>2 Q. You'll say "okay" or do you know one way</p> <p>3 or the other?</p> <p>4 A. So for me to sit here and tell you that</p> <p>5 specifically refers to that, without going back to</p> <p>6 the reference, I can't tell you.</p> <p>7 Q. So you would have to look at Section 502</p> <p>8 of the FD&C Act in order to know whether it deals</p> <p>9 with misbranded drugs and devices?</p> <p>10 A. Right. Just to make sure I'm giving you</p> <p>11 a correct answer.</p> <p>12 MR. DAVIS: Objection;</p> <p>13 mischaracterizes testimony.</p> <p>14 (Discussion off the written record.)</p> <p>15 MS. ISIDRO: Okay. So let's go ahead</p> <p>16 and mark this as Exhibit 12?</p> <p>17 MR. DAVIS: I think -- 11, I think.</p> <p>18 (Exhibit 11 was marked.)</p> <p>19 Q. And we've marked as Exhibit 11 a copy of</p> <p>20 Sections 501 and 502 of the FD&C Act. And looking</p> <p>21 at Exhibit 11, can you now confirm that Section 501</p> <p>22 of the FD&C Act has to do with adulterated drugs and</p> <p>23 devices?</p> <p>24 A. I can.</p> <p>25 Q. And can you now confirm that Section 502</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. It's a quote from the act or from a</p> <p>2 guidance document?</p> <p>3 A. Like I said, I'm not sure. It was one of</p> <p>4 the documents I reviewed. It may have been in</p> <p>5 another one of the documents I footnoted elsewhere.</p> <p>6 I just didn't put a footnote here.</p> <p>7 Q. Okay. So focusing on the FD&C Act,</p> <p>8 Section 501 has to do with adulterated drugs and</p> <p>9 devices. Correct?</p> <p>10 A. I'm not certain. I don't memorize these</p> <p>11 numbers.</p> <p>12 Q. Does Section 502 have to do with</p> <p>13 misbranded drugs and devices?</p> <p>14 A. Again we'll have to pull it up to look at</p> <p>15 that.</p> <p>16 Q. As you sit here right now, without</p> <p>17 looking at it, you're not sure one way or the other?</p> <p>18 A. Well, I've got like a hundred references</p> <p>19 here. And so if we're speaking to exactly what one</p> <p>20 of them specifically states, we need to pull it up</p> <p>21 and look at it and we can review it.</p> <p>22 Q. No. My question was just does</p> <p>23 Section 502 of the FD&C Act have to do with</p> <p>24 misbranded drugs and devices?</p> <p>25 A. Okay. We haven't looked at that, but</p>	<p style="text-align: right;">Page 137</p> <p>1 of the FD&C Act has to do with misbranded drugs and</p> <p>2 devices?</p> <p>3 A. That's -- that is correct.</p> <p>4 Q. And you can take as much time as you need</p> <p>5 to look through this, but is your quoted language</p> <p>6 from Paragraph 25, does it appear anywhere in</p> <p>7 Sections 501 or 502 of the FD&C Act?</p> <p>8 MR. DAVIS: Do you want a moment to</p> <p>9 review the document?</p> <p>10 A. Yes. Because like I said -- like I told</p> <p>11 you before, I'm not certain it came from this</p> <p>12 document, because I'm not sure where it came from.</p> <p>13 It may have come from another document like we</p> <p>14 reviewed this morning. But I'll be glad to look at</p> <p>15 this.</p> <p>16 Q. As I said, feel free to look through it</p> <p>17 and just let me know one way or the other whether</p> <p>18 the language in Paragraph 25 comes from either of</p> <p>19 these sections in Exhibit 11.</p> <p>20 A. (Pause.)</p> <p>21 THE VIDEOGRAPHER: Off the record,</p> <p>22 2:09 p.m.</p> <p>23 (Break.)</p> <p>24 THE VIDEOGRAPHER: Back on the</p> <p>25 record, 2:11 p.m. 0</p>

<p style="text-align: right;">Page 138</p> <p>1 Q. Mr. Quick, when we went off the record 2 you were taking some time to look through Exhibit 11 3 to see whether the quote in Paragraph 25 came from 4 either of the sections that are in Exhibit 11. 5 Did you have sufficient time to review? 6 Do you need additional time? 7 A. I don't see that section in here. I 8 didn't indicate it was here, so I'm not -- but I 9 don't see it here, to answer your question. 10 Q. Okay. 11 MR. DAVIS: If you like, on the next 12 break we can look for it and see what he's referring 13 to and get back to you on that. 14 Q. All right. Focusing on the last sentence 15 of Paragraph 25, that states that: A facility must 16 have in place systems that ensure proper design, 17 monitoring, and control of manufacturing processes 18 and facilities. 19 Correct? 20 A. That's what the statement says. 21 Q. Does that refer to SOPs? 22 A. It probably refers to a number of 23 different things. The systems -- the manufacturing 24 system -- the manufacturing operation has got to be 25 in control, and it talks about the processes and</p>	<p style="text-align: right;">Page 140</p> <p>1 Q. To quality. 2 A. I mean, quality is a large topic. What 3 specific aspect of quality? 4 Q. Any aspect of quality. 5 A. Well, I'm sure that they have SOPs that 6 refer to some aspect of quality. You'd almost have 7 to have that. So, I mean -- I'm not sure -- your 8 question really doesn't make any sense. 9 Q. In your answer there you're making an 10 assumption, right, when you say "I'm sure that." 11 Am I interpreting that correctly? You're 12 making an assumption that they would -- 13 A. An assumption, yes. 14 Q. But you haven't specifically reviewed any 15 SOP of any of the defendants relating to any aspect 16 of quality? 17 A. No, I didn't say that. What I said was 18 there may have been SOPs in the documents I 19 reviewed. They're in the list here. There may have 20 been SOPs in some of those documents. I'm just 21 not -- I just don't recall that. 22 Q. Are you familiar with Section -- with 23 21 U.S. Section 352? 24 A. That number doesn't -- I don't recall 25 exactly what that number would be referring to.</p>
<p style="text-align: right;">Page 139</p> <p>1 facilities, so part of that would be SOPs. But 2 you've got to follow the SOPs. 3 Q. Did you review defendants' SOPs in 4 forming your opinions in this litigation? 5 MR. DAVIS: Objection to the use of 6 the word "this litigation." 7 A. So -- 8 MR. DAVIS: You can answer. 9 A. -- I'm not sure whether any of these 10 reference documents included SOPs or not. I know 11 I've requested SOPs, but I'm not sure whether I 12 reviewed those SOPs in the context of this 13 declaration. 14 Q. As you sit here today, are you aware of 15 whether any specific defendant had a quality policy 16 in place? 17 MR. DAVIS: Objection; vague. 18 You can answer. 19 A. I'm not. I'm not quite sure what you're 20 asking. No, I did not look at whether they had a 21 quality policy or not. 22 Q. As you sit here today, are you aware of 23 whether any defendant in this litigation had an SOP 24 relating directly to quality? 25 A. Relating to what?</p>	<p style="text-align: right;">Page 141</p> <p>1 Is that a document I referenced? 2 Q. Let's go ahead and mark a copy of 3 21 U.S.C. 352 as Exhibit 12. 4 MR. DAVIS: I think we already have 5 that marked here in Exhibit 11. 6 MS. ISIDRO: We do? 7 MR. DAVIS: Yeah. Section 502 is 8 21 U.S.C. 352. 9 MS. ISIDRO: Let's go ahead and mark 10 this copy anyway, Exhibit 12. 11 (Exhibit 12 was marked.) 12 Q. And 21 U.S.C. 352 deals with misbranded 13 drugs and devices. Correct? 14 A. I didn't -- I didn't hear the question. 15 Would you repeat it? 16 Q. 21 U.S.C. 352 deals with misbranded drugs 17 and devices. Correct? 18 A. That's correct, yes. 19 Q. Does it -- does 21 U.S.C. 352 mention 20 anything with respect to purity of a drug product? 21 A. If we want to spend the time to review 22 this we can, but I don't recall. 23 Q. As you sit here today, you don't know one 24 way or the other? 25 A. Well, it may. If you want me to read the</p>

<p style="text-align: right;">Page 142</p> <p>1 document --</p> <p>2 MR. DAVIS: Yeah. Why don't you take</p> <p>3 a few minutes to read the document.</p> <p>4 A. (Pause.)</p> <p>5 I don't see a reference to purity in this</p> <p>6 document.</p> <p>7 Q. There's no reference to purity, there's</p> <p>8 no reference to impurities. Correct?</p> <p>9 A. I didn't see that in the document, yes.</p> <p>10 Q. FDA actually allows for the presence of</p> <p>11 some unidentified or unspecified impurities with a</p> <p>12 drug product below a certain threshold. Correct?</p> <p>13 MR. DAVIS: Objection; vague, and</p> <p>14 incomplete question.</p> <p>15 You can answer.</p> <p>16 A. So that's not an area I was opining on,</p> <p>17 in terms of whether they allow or don't allow that.</p> <p>18 That may be the case, but that's not an area I was</p> <p>19 opining on.</p> <p>20 Q. And so, as you sit here today, you can't</p> <p>21 speak to that one way or the other?</p> <p>22 A. I can't speak to that. Right.</p> <p>23 Q. The purity of an API product is shown on</p> <p>24 the certificate of analysis. Correct?</p> <p>25 MR. DAVIS: Objection; vague, again.</p>	<p style="text-align: right;">Page 144</p> <p>1 You can answer.</p> <p>2 A. So I know where you're going to go with</p> <p>3 this. So the -- the --</p> <p>4 Q. I'm going to ask you to not try and guess</p> <p>5 where I'm going with any question.</p> <p>6 A. Okay.</p> <p>7 Q. If you could just stick to answering --</p> <p>8 A. I'm not --</p> <p>9 Q. -- questions that are asked.</p> <p>10 A. I'm not sure. I haven't looked at what</p> <p>11 actually is required on the labeling other than --</p> <p>12 no.</p> <p>13 Q. Okay. So do you know one way or the</p> <p>14 other whether labeling of product potency within</p> <p>15 allowable limits is required by FDA?</p> <p>16 MR. DAVIS: Object to form.</p> <p>17 You can answer.</p> <p>18 A. If potency is what?</p> <p>19 Q. Do you know one way or the other whether</p> <p>20 labeling of product potency within allowable limits</p> <p>21 is required by FDA?</p> <p>22 A. Well, the potency would be on the</p> <p>23 labeling.</p> <p>24 Q. And that is required by FDA. Right?</p> <p>25 A. Well, again, that's not something I'm</p>
<p style="text-align: right;">Page 143</p> <p>1 You can answer.</p> <p>2 A. So certificate of analysis has a number</p> <p>3 of -- number of things that are reported on the</p> <p>4 certificate of analysis.</p> <p>5 Q. And is purity of the API one of the</p> <p>6 things?</p> <p>7 MR. DAVIS: Objection.</p> <p>8 A. Well, typically it would be potency,</p> <p>9 other things in there. Purity is probably not</p> <p>10 something that would be on the C of A.</p> <p>11 Q. You say "probably" does that --</p> <p>12 A. I --</p> <p>13 Q. You're not sure one way or the other?</p> <p>14 A. I'm not sure.</p> <p>15 Q. Okay. Are you aware whether at any time</p> <p>16 any valsartan products or valsartan-containing</p> <p>17 products were determined to be subpotent by the FDA?</p> <p>18 A. I'm not aware of any situation. I mean,</p> <p>19 that doesn't mean it didn't happen, I'm just not</p> <p>20 aware of it.</p> <p>21 Q. Now, labeling of allowable impurities or</p> <p>22 disclosing impurities in any amount on a marketed</p> <p>23 drug product label is not something that's required</p> <p>24 in an ANDA. Correct?</p> <p>25 MR. DAVIS: Object to form.</p>	<p style="text-align: right;">Page 145</p> <p>1 opining on but, yes, I would assume so.</p> <p>2 Q. Okay. At any time did FDA require any</p> <p>3 manufacturer to change it -- its approved labeling</p> <p>4 to declare that NDMA or NDEA be listed as impurities</p> <p>5 on their a valsartan product labels?</p> <p>6 A. I don't know.</p> <p>7 Q. Mr. Quick, you're not taking the position</p> <p>8 that any manufacturer ever purposefully added NDMA</p> <p>9 or NDEA to their products as part of their</p> <p>10 formulation. Correct?</p> <p>11 A. That they knowingly and purposely added,</p> <p>12 no, I'm not taking that position.</p> <p>13 Q. Okay. And you're not offering any</p> <p>14 opinions on the content of any of the valsartan</p> <p>15 lab -- product labels. Correct?</p> <p>16 A. Other than the fact that I made the</p> <p>17 comment that they're misbranded.</p> <p>18 Q. Now, let's take a look at Paragraph 30 in</p> <p>19 your report.</p> <p>20 A. Okay.</p> <p>21 Q. You state in Paragraph 30 that: Because</p> <p>22 the presence of NDMA and/or NDEA was not revealed in</p> <p>23 the labeling, advertisements and/or patient booklets</p> <p>24 given to consumers at the time of dispensing, this</p> <p>25 also resulted in defendants' valsartan products</p>

<p style="text-align: right;">Page 146</p> <p>1 being misbranded.</p> <p>2 A. That's what it says.</p> <p>3 Q. What is your basis for that statement?</p> <p>4 A. Because it's different from what the</p> <p>5 branded product was, the Novartis product which did</p> <p>6 not have these contaminants.</p> <p>7 Q. Do you know whether the branded product</p> <p>8 was ever tested for NDMA or NDEA prior to July</p> <p>9 of 2018?</p> <p>10 A. Well, what I do know is that Novartis</p> <p>11 tested the ZHP product and found a contaminate in</p> <p>12 June of 2018.</p> <p>13 Q. Do you know whether Novartis's product,</p> <p>14 Novartis's brand product, was ever tested for the</p> <p>15 presence of NDMA or NDEA prior to July of 2018?</p> <p>16 A. I do not know.</p> <p>17 THE WITNESS: Could we take like a</p> <p>18 five -- five-minute break?</p> <p>19 MS. ISIDRO: Sure.</p> <p>20 THE VIDEOGRAPHER: Off the record.</p> <p>21 The time is 2:27 p.m.</p> <p>22 (Break.)</p> <p>23 THE VIDEOGRAPHER: Back on the</p> <p>24 record. The time is 2:39 p.m.</p> <p>25 Q. Mr. Quick, we've talked about CGMPs a bit</p>	<p style="text-align: right;">Page 148</p> <p>1 mentioned --</p> <p>2 A. I did.</p> <p>3 Q. -- warning letters?</p> <p>4 A. Warning letters would typically have</p> <p>5 that. Maybe not all warning letters, but warning</p> <p>6 letters typically would.</p> <p>7 (Reporter admonishment.)</p> <p>8 Q. Do you recall receiving any warning</p> <p>9 letters from the FDA during your time at Baxter?</p> <p>10 A. Yes.</p> <p>11 MS. ISIDRO: Let's go ahead and mark</p> <p>12 as Exhibit 13, a August 11th, 2000, warning letter,</p> <p>13 CHI-29-00.</p> <p>14 (Exhibit 13 was marked.)</p> <p>15 Q. I'll give you a moment to take a look at</p> <p>16 Exhibit 13. But when you're ready, this is a</p> <p>17 warning letter that was sent to Baxter. Correct?</p> <p>18 A. It was a warning letter sent to Baxter,</p> <p>19 yes.</p> <p>20 Q. And this was during your time at Baxter?</p> <p>21 A. That's correct.</p> <p>22 Q. In fact, you're cc'd at the bottom of the</p> <p>23 warning letter. Correct?</p> <p>24 A. That's correct.</p> <p>25 Q. Do you recall receiving this letter?</p>
<p style="text-align: right;">Page 147</p> <p>1 today. Right?</p> <p>2 A. We have.</p> <p>3 Q. The C in CGMPs stands for "current."</p> <p>4 Right?</p> <p>5 A. That's right.</p> <p>6 Q. And that requires companies to use</p> <p>7 technologies and systems that are up-to-date at the</p> <p>8 current time. Right? The respective current time?</p> <p>9 A. Well, current refers to current. So...</p> <p>10 Q. Look, you say in your report: The C in</p> <p>11 CGMPs as standing for current, requiring companies</p> <p>12 to use technologies and systems that are --</p> <p>13 A. Right.</p> <p>14 Q. -- "up-to-date in order to comply with</p> <p>15 the regulations..."</p> <p>16 A. Right. That's correct.</p> <p>17 Q. And then, with respect to Paragraph 32, I</p> <p>18 believe you stated earlier that if pulling up any</p> <p>19 warning letter would be -- that basically any</p> <p>20 warning letter would provide support for that</p> <p>21 statement. Right?</p> <p>22 A. Well, we also pulled up the other</p> <p>23 document from FDA that stated the same thing this</p> <p>24 morning, if you remember.</p> <p>25 Q. Okay. But you had -- you had</p>	<p style="text-align: right;">Page 149</p> <p>1 A. We're talking something that occurred 22</p> <p>2 years ago. I don't -- no, I don't recall actually</p> <p>3 receiving it. I'm sure I did.</p> <p>4 Q. And this letter discusses that: During</p> <p>5 in -- inspection conducted at one of Baxter's</p> <p>6 facilities, the investigators found serious</p> <p>7 deviations from the current good manufacturing</p> <p>8 practice regulations.</p> <p>9 Correct?</p> <p>10 A. Where -- where are you reading?</p> <p>11 Q. In the first paragraph of the letter.</p> <p>12 A. The first paragraph. Okay.</p> <p>13 (Discussion off the written record.)</p> <p>14 Q. I'm just giving you a moment to read.</p> <p>15 When you're ready to proceed, let me know.</p> <p>16 A. (Pause.)</p> <p>17 Okay.</p> <p>18 Q. So you would agree that this letter</p> <p>19 discusses that during inspection conducted at one of</p> <p>20 Baxter's facilities, the investigators found a</p> <p>21 series of deviations from the current good</p> <p>22 manufacturing practice regulations?</p> <p>23 A. That's what it says, yes.</p> <p>24 Q. And, in fact, it says: They found</p> <p>25 serious deviations from the current good</p>

<p style="text-align: right;">Page 150</p> <p>1 manufacturing practice regulations. 2 Correct? 3 A. That's what it says, yes. 4 Q. It goes on to enumerate a number of those 5 deviations. Right? 6 A. It does. 7 Q. And it also says on the last page that: 8 The CGMP deviations that are identified are not to 9 be considered an all inclusive list of the 10 deficiencies at the facility. 11 Right? 12 A. That's correct. That's what it says. 13 Q. Does the letter say anything about any 14 and every product that Baxter made at the same time 15 as -- as the observation that the investigators made 16 were adulterated? 17 MR. DAVIS: Objection. 18 A. It does. First paragraph. 19 Q. Did you consider, at the time that you 20 received this letter, that each and every product 21 that was made at that facility during the time that 22 these observations were in effect, were adulterated? 23 A. We assumed that this applied to all the 24 products that were made at the facility, yes, we 25 did.</p>	<p style="text-align: right;">Page 152</p> <p>1 and the specific drugs involved? 2 MR. DAVIS: Objection to form, and 3 incomplete hypothetical. 4 A. So I'm not quite sure I understand what 5 you mean by the question. 6 Q. Would you agree with that statement? 7 A. Well, I don't understand the statement. 8 Q. Are you aware of whether FDA has ever 9 said that the impact of CGMP violations depends on 10 the nature of those violations and on the specific 11 drugs involved? 12 A. I haven't seen that specific statement. 13 Q. Let's look at Paragraph 41 of your 14 report. 15 A. 41? 16 Q. Uh-huh. 17 A. Okay. 18 Q. You state in Paragraph 41 that: The 19 decisions of the quality function should never be 20 overridden by higher levels of management. 21 Correct? 22 A. That's correct. 23 Q. When you say "quality function" there, 24 are you referring to the quality unit? 25 A. I'm referring to the quality function.</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. Did the facility go on to, for example, 2 recall all of the product that it had on the market 3 at the time that had been manufactured at that 4 facility? 5 A. Well, there's no recall. But to answer 6 your question, we did consider all the products to 7 be adulterated. 8 Q. Did it put a distribution hold on all 9 product manufactured at the facility? 10 A. No, we did not. 11 Q. And so you didn't initiate a recall, and 12 you didn't initiate in -- a distribution hold, yet 13 you considered all product manufactured at that 14 facility to be -- 15 A. We -- 16 Q. -- adulterated? 17 A. So we took this letter very seriously. 18 Q. So, again, my question was, you didn't 19 initiate a recall, and you didn't initiate a 20 distribution hold, yet you considered all of the 21 product manufactured at that facility to be 22 adulterated? 23 A. Under the context of this, yes. 24 Q. Would you agree that the impact of CGMP 25 violations depends on the nature of those violations</p>	<p style="text-align: right;">Page 153</p> <p>1 Q. Are you familiar with something that is 2 called the "quality unit" and is referenced in 3 21 CFR 211? 4 A. Yes. 5 Q. Is that what you understand to be the 6 quality function? 7 A. They would be one and the same. 8 Q. Okay. 9 A. So just to clarify that point. 10 Q. Uh-huh. 11 A. The intent is if the quality 12 decision makes -- if the quality unit makes the 13 decision, it should not be overridden by management 14 for any reason, senior management. That's the 15 intent of that statement. They should have total 16 autonomy to make those decisions. 17 Q. Are you saying that there are no 18 possibilities under which management might have to 19 intervene in order to affirm the integrity of the 20 corporate quality system? 21 MR. DAVIS: Objection; misrepresents 22 the testimony. 23 A. That's not what I said. 24 Q. Well, let me make sure I understand. 25 You said that if the quality unit makes a</p>

<p style="text-align: right;">Page 154</p> <p>1 decision, it should not be overridden by management, 2 senior management for any reason. Correct? 3 A. That is correct, yes. 4 Q. What if senior management believes that 5 it is necessary to override the quality unit's 6 decision in order to affirm the integrity of the 7 corporate quality system? 8 MR. DAVIS: Objection to form, and 9 incomplete hypothetical. 10 You can answer. 11 A. Well, what you just said makes absolutely 12 no sense. 13 Q. So it's your position that there is no 14 possibility that senior management would ever need 15 to intervene for legitimate reasons while also 16 affirming the corporate quality system? 17 A. The last part of your statement just 18 contradicts the first part, so let me clarify this. 19 Okay? 20 Is that it's certainly acceptable for 21 senior management to have a discussion with the 22 quality unit about the decision, but they should not 23 override that decision. 24 Q. Your statement requires an assumption 25 that the quality unit or the quality functions'</p>	<p style="text-align: right;">Page 156</p> <p>1 it's a problem with senior management then. 2 Q. Well, you, yourself, said "unless you've 3 got a quality person that's totally incompetent 4 that's gone rogue. If you've got that situation, 5 you've got a much bigger problem." 6 But if you've got that situation, should 7 senior management intervene? 8 A. Well, if you have that situation, then 9 management probably should intervene. You should 10 probably have a new quality person there. But that 11 should never have happened in the first place, 12 because management should have been following what 13 the quality function is doing, and they should have 14 recognized that problem before then. So that's -- 15 this situation should never occur. 16 Q. Once the problem -- if there is a 17 problem, once that problem is recognized, senior 18 management should intervene. Right? 19 A. No, that's not what I said. 20 Q. Are you saying that if senior management 21 recognizes a problem, it should not intervene? 22 A. What I said was, the quality unit's 23 decision should almost always be final. 24 Your hypothesis here is you've got a 25 quality person that doesn't know what they're doing</p>
<p style="text-align: right;">Page 155</p> <p>1 decisions are always right. Correct? 2 A. I'm saying that they are the final 3 decision, they should be the final decision. What 4 I'm saying, as I said before, it's perfectly 5 acceptable for senior management to have a 6 discussion with the quality unit, why did you make 7 this decision, let's talk about it. 8 But at the end of the day, the quality 9 unit should not be overridden by the decision. 10 Q. Under any circumstances? 11 A. Well, unless you've got a -- unless 12 you've got a quality person that's totally 13 incompetent and that's gone rogue, I mean, which if 14 you've got that situation, you have got a much 15 bigger problem in the company. 16 Q. And if you had that situation, would it 17 be appropriate for senior management to intervene? 18 MR. DAVIS: Objection; incomplete 19 hypothetical. 20 But you can answer. 21 THE WITNESS: Okay. 22 A. That is a crazy question, and the reason 23 that it's crazy is because senior management should 24 not have somebody in that position to begin with 25 that's not going to make intelligent decisions. So</p>	<p style="text-align: right;">Page 157</p> <p>1 or is incompetent or the other thing. And my point 2 is, if that's the case, the management of the 3 company should have done something well before a 4 problem ever occurred in the first place. 5 Q. You say "The quality unit's decision 6 should almost always be final." 7 A. And that's correct. 8 Q. Almost always is not always. Right? 9 A. In the unlikely event as to what you said 10 here, if you've got -- I mean, if quality function 11 is often on a wild -- I mean, a rogue quality person 12 who's making erroneous decisions, that person should 13 not have been in that job in the first place, and 14 that person should have been replaced by management 15 is what I'm saying. 16 But the typical aspect would be the 17 quality -- here's the real point, is that in a lot 18 of companies, senior management will override 19 quality's decision because of business 20 considerations which should never be done. 21 It's okay to have a discussion with the 22 quality head, but you don't want to override that 23 quality unit's decision. That's the whole point 24 here. 25 THE WITNESS: I'm sorry. Am I going</p>

<p style="text-align: right;">Page 158</p> <p>1 too fast?</p> <p>2 THE STENOGRAPHER: You're fine.</p> <p>3 Q. All right. Let's go to Subheading 3 of</p> <p>4 your report, where you talk about: Comprehensive</p> <p>5 Quality Management System.</p> <p>6 A. Okay.</p> <p>7 Q. Still on Page 10.</p> <p>8 A. Sure.</p> <p>9 Q. At Paragraph 44, you discuss the topic of</p> <p>10 SOPs as an element that's essential to forming the</p> <p>11 core of a quality system. Correct?</p> <p>12 A. Yes.</p> <p>13 Q. And at the top of Page 11, still under</p> <p>14 Paragraph 44, you list some specific --</p> <p>15 A. Pertinent examples.</p> <p>16 Q. -- examples of SOPs that a company should</p> <p>17 have. Correct?</p> <p>18 A. Among others, yes.</p> <p>19 Q. Each individual manufacturer establishes</p> <p>20 its own SOPs. Correct?</p> <p>21 A. They should.</p> <p>22 Q. And so SOPs can and do vary from one</p> <p>23 manufacturer to another. Right?</p> <p>24 MR. DAVIS: Objection; asked and</p> <p>25 answered earlier this morning.</p>	<p style="text-align: right;">Page 160</p> <p>1 A. I'm not certain, but they should have had</p> <p>2 these.</p> <p>3 Q. As you sit here today, do you know one</p> <p>4 way or the other whether any defendant in this</p> <p>5 litigation had SOPs on deviations or</p> <p>6 nonconformances?</p> <p>7 A. I'm not certain. But let me just</p> <p>8 interject here for a second. The real issue is</p> <p>9 whether they were following their own SOPs or not.</p> <p>10 That's the real issue.</p> <p>11 Q. As you sit here today, do you know</p> <p>12 whether any defendant in this litigation had SOPs</p> <p>13 regarding out-of-specification results?</p> <p>14 A. Again, same answer to the ones before,</p> <p>15 they should have had these SOPs. Whether they</p> <p>16 actually have them, I'm not certain. I mean, I know</p> <p>17 some of these probably did, because some of these</p> <p>18 are referenced at various places, but for me to tell</p> <p>19 you for all of the defendants whether they had all</p> <p>20 of these SOPs, I don't know whether they had all of</p> <p>21 these SOPs. My assumption is they probably did.</p> <p>22 Q. Okay. And is your answer the same with</p> <p>23 respect to all of the categories that you list at</p> <p>24 the top of Page 11 --</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 159</p> <p>1 But you can answer it again.</p> <p>2 A. Well, of course they're going to vary,</p> <p>3 because they're not all written by the same person,</p> <p>4 but they should all be compliant with the</p> <p>5 regulations and guidances.</p> <p>6 Q. As you sit here today, do you know</p> <p>7 whether any of the defendants in this litigation had</p> <p>8 SOPs on risk management?</p> <p>9 A. I believe that there were some, yes.</p> <p>10 Q. Are you aware of whether all defendants</p> <p>11 had SOPs on risk management?</p> <p>12 A. I'm not certain whether they did or not.</p> <p>13 They should have had those SOPs. Whether they</p> <p>14 actually had them, I'm not sure.</p> <p>15 Q. As you sit here today, do you know one</p> <p>16 way or the other whether any particular defendant in</p> <p>17 this litigation had SOPs regarding incoming raw</p> <p>18 materials and release?</p> <p>19 A. If they had incoming what?</p> <p>20 Q. The second category at the top of</p> <p>21 Page 11.</p> <p>22 A. Oh, okay. Okay.</p> <p>23 Q. As you sit here today, do you know</p> <p>24 whether any defendant in this litigation had SOPs on</p> <p>25 incoming raw materials and release?</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. -- of your report?</p> <p>2 A. So I'll add a comment to that, though.</p> <p>3 The real question in many cases is whether they were</p> <p>4 adequate or not.</p> <p>5 Q. Would someone be able to determine an</p> <p>6 SOP's adequacy without reviewing it?</p> <p>7 A. Without reviewing it?</p> <p>8 Q. Uh-huh.</p> <p>9 A. I mean, if you're going to determine it</p> <p>10 to not be adequate, you'd have to review it, I mean,</p> <p>11 or know the outcome, if it wasn't the right outcome.</p> <p>12 I...</p> <p>13 Q. Let's go to Paragraph 46 of your report.</p> <p>14 You state in Paragraph 46 that: The number one</p> <p>15 citation by FDA year after year is the following,</p> <p>16 quote, procedures not in writing, comma, fully</p> <p>17 followed, end quote.</p> <p>18 Right?</p> <p>19 A. Right, that's what it says.</p> <p>20 Q. And you cite to a specific website</p> <p>21 immediately following that. Is that the reference</p> <p>22 from which that quote comes?</p> <p>23 A. Yes.</p> <p>24 Q. And the website that's referenced there</p> <p>25 in that paragraph, Footnote 15, is that an</p>

<p style="text-align: right;">Page 162</p> <p>1 inspection observations website?</p> <p>2 A. What it is, it's a list -- it goes</p> <p>3 through 21 CFR 211, and it lists the number of times</p> <p>4 a firm has been cited for each of the areas, and the</p> <p>5 failure to follow procedures or not having had the</p> <p>6 procedures, it's always at the top of the list for</p> <p>7 the number of instances where there have been</p> <p>8 citations.</p> <p>9 Q. Let's go ahead and mark as --</p> <p>10 MR. DAVIS: 14.</p> <p>11 Q. -- Exhibit 14 this web page with the</p> <p>12 title: Inspection Observations.</p> <p>13 (Exhibit 14 was marked.)</p> <p>14 Q. Reviewing the content of this exhibit, is</p> <p>15 this what you're referring to in Footnote 15?</p> <p>16 A. I'm not certain. I'm looking at the</p> <p>17 bottom. It doesn't appear to be the same as the</p> <p>18 reference footnote.</p> <p>19 Q. You are correct. The URL is not the same</p> <p>20 and I'll represent to you that when you type in the</p> <p>21 URL in Footnote 15 --</p> <p>22 A. Okay.</p> <p>23 Q. -- it automatically redirects to the</p> <p>24 footnote at the bottom of Exhibit 14.</p> <p>25 MS. HILTON: I'll confirm.</p>	<p style="text-align: right;">Page 164</p> <p>1 different warning letters. Correct?</p> <p>2 A. I do.</p> <p>3 Q. And these warning letters were issued to</p> <p>4 two different firms?</p> <p>5 A. That's correct.</p> <p>6 Q. Are you aware of whether either of those</p> <p>7 firms made or makes valsartan-containing products?</p> <p>8 A. I don't believe. I don't know for</p> <p>9 certain, but I don't believe either one of these</p> <p>10 make valsartan.</p> <p>11 Q. Okay. And do these -- do these warning</p> <p>12 letters have anything to do with nitrosamines at</p> <p>13 all?</p> <p>14 A. As far as I know, they do not. That was</p> <p>15 not the intent of the reference.</p> <p>16 Q. Okay. Are you aware whether either of</p> <p>17 the firms who received these warning letters that</p> <p>18 are referenced in Paragraph 47 manufactured solid</p> <p>19 oral dose products?</p> <p>20 A. I'm not certain.</p> <p>21 Q. Okay.</p> <p>22 A. They may. I'm not certain. But that was</p> <p>23 not really the relevance to putting that in, in the</p> <p>24 first place. The relevance was the fact that they</p> <p>25 were cited for not using proper risk management.</p>
<p style="text-align: right;">Page 163</p> <p>1 Q. So can you point me to where this quote</p> <p>2 appears in this inspection observations web page?</p> <p>3 A. So in order to find that, you have to</p> <p>4 click on the link for the specific year and then it</p> <p>5 will detail out in order of occurrence the</p> <p>6 observations and what they were for.</p> <p>7 Q. So your statement that the number one</p> <p>8 citation by FDA, year after year, is based on your</p> <p>9 review of the information that appears in each of</p> <p>10 those links for any given year?</p> <p>11 A. So I did not go back and review every</p> <p>12 single year here, but historically -- and I review</p> <p>13 this periodically -- that it's typically the number</p> <p>14 one citation for failure to follow your own</p> <p>15 procedures.</p> <p>16 Q. So that's based on your experience?</p> <p>17 A. My experience. But, I mean, that's --</p> <p>18 you can go to the website and you will see the</p> <p>19 number of occurrences and what they were for. And</p> <p>20 these are always at the top of the list, in terms of</p> <p>21 number of occurrences.</p> <p>22 Q. Okay. Let's go to Paragraph 47 in your</p> <p>23 report.</p> <p>24 A. Okay.</p> <p>25 Q. In that paragraph you refer to two</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. Let's go to Section E of your report.</p> <p>2 A. Section what?</p> <p>3 Q. Section E, as in Edward.</p> <p>4 A. Okay.</p> <p>5 Q. At Paragraph 76, and continuing through</p> <p>6 Paragraph 95, your report recounts the type of</p> <p>7 inspections that FDA conducts, right, and the</p> <p>8 possible outcomes of those inspections?</p> <p>9 A. I do.</p> <p>10 Q. And it talks about what possible outcomes</p> <p>11 might ensue if the FDA were to conclude that an</p> <p>12 official action was indicated or an OAI status was</p> <p>13 indicated. Correct?</p> <p>14 A. I do.</p> <p>15 Q. Are you aware of whether any of the</p> <p>16 facilities that manufactured valsartan-containing</p> <p>17 products for the U.S. in the 2012 to the 2018 time</p> <p>18 period were ever formally classified as OAI by FDA?</p> <p>19 A. Yes.</p> <p>20 Q. Which ones?</p> <p>21 A. Well, I know ZHP was. And there may be</p> <p>22 others, but I know ZHP was.</p> <p>23 Q. In the time period from 2012 to July</p> <p>24 2018?</p> <p>25 A. The 2018 inspection was classified OAI.</p>

<p style="text-align: right;">Page 166</p> <p>1 Q. When did that inspection occur? When in 2 2018?</p> <p>3 A. It was the summer of 2018.</p> <p>4 Q. Okay. Are you aware of any others?</p> <p>5 A. There may be others. I'm not certain.</p> <p>6 Q. As you sit here today, you're not aware 7 of any others?</p> <p>8 A. Well, I mean, it's not something I looked 9 at and reviewed.</p> <p>10 Q. So as you sit here today, you're not 11 aware of any others?</p> <p>12 A. That I can speak definitively to, yes, 13 you're right. That doesn't mean there weren't any. 14 And I suspect that the warning letters -- 15 typically a warning letter would not be issued 16 unless there was an OAI inspection. And a number of 17 these firms had warning letters.</p> <p>18 Q. Are you speculating right now?</p> <p>19 A. I'm just telling you, typically a warning 20 letter would not be issued unless there was an OAI 21 inspection. So a warning letter would not 22 usually -- a warning letter would very seldom ever 23 be issued for a VAI inspection.</p> <p>24 Q. But, again, as you sit here today, you're 25 not aware of that particular situation occurring</p>	<p style="text-align: right;">Page 168</p> <p>1 common to every valsartan product purchased by the 2 class members. Do you see that?</p> <p>3 A. I see that.</p> <p>4 Q. I'm going to ask you about a few 5 different portions of that sentence.</p> <p>6 When you say that you reviewed a set of 7 documents related to defendants' noncompliance with 8 CGMPs, what are you referring to?</p> <p>9 A. I'm referring to examples of 10 noncompliance with GMPs. It wasn't all exhaustive. 11 There were examples.</p> <p>12 Q. How did you determine which examples you 13 would review?</p> <p>14 A. Well, there is no specific determination. 15 I went through all the defendants and I pulled out 16 examples that I thought were representative of what 17 I considered to be serious examples -- serious GMP 18 situations.</p> <p>19 Q. And the ones that you pulled out are the 20 ones that are listed in your report?</p> <p>21 A. They are.</p> <p>22 Q. Okay. And in the second part of that 23 sentence it says that you went through that 24 exercise: In order to determine whether these 25 examples of noncompliance with CGMPs are the type</p>
<p style="text-align: right;">Page 167</p> <p>1 with any defendant other than what you have 2 identified?</p> <p>3 A. It's not something I specifically 4 reviewed.</p> <p>5 Q. Okay. So you're not aware --</p> <p>6 A. I -- okay.</p> <p>7 MS. ISIDRO: Let's go ahead and take 8 a five-minute break.</p> <p>9 THE VIDEOGRAPHER: Off the record. 10 The time is 3:10 p.m. 0 11 (Break.)</p> <p>12 THE VIDEOGRAPHER: Back on the 13 record. The time is 3:26 p.m.</p> <p>14 Q. All right. Mr. Quick, let's turn to 15 Section G of --</p> <p>16 A. Section what?</p> <p>17 Q. G as in girl, in your report. 18 (Discussion off the written record.)</p> <p>19 Q. You state in Paragraph 101 -- 20 (Discussion off the written record.)</p> <p>21 Q. So, Mr. Quick, you state in Paragraph 101 22 that you have reviewed a set of documents related to 23 defendants' noncompliance with CGMPs in order to 24 determine whether these examples of noncompliance 25 with CGMPs are the type that would impact and be</p>	<p style="text-align: right;">Page 169</p> <p>1 that would impact and be common to every valsartan 2 product purchased by the class members.</p> <p>3 What do you mean by that?</p> <p>4 A. Well, I mean, we were talking about GMP 5 situations, not like somebody not wearing a hairnet. 6 Okay? That would not be what I would be talking 7 about here. These would be something that would 8 apply to everything.</p> <p>9 Q. So is it your position that a purported 10 noncompliance with respect to ZHP's API would impact 11 a product that contained Mylan's API?</p> <p>12 MR. DAVIS: Objection; 13 mischaracterizes his report.</p> <p>14 A. So when I refer -- for example, relative 15 to ZHP and, for example, Teva purchasing ZHP, we 16 were talking about all of the ZHP relative to Teva 17 that would apply to all of the class relative to 18 that situation.</p> <p>19 Q. So it's your position that the examples 20 that you've provided with respect to ZHP would 21 impact any product that utilized ZHP's API?</p> <p>22 A. Well, yes. But to answer the question 23 you brought it out for, am I going back to say 24 relative to -- and, for example, the situation of 25 Teva and Mylan, I'm not referring back to Mylan,</p>

<p style="text-align: right;">Page 170</p> <p>1 that's a separate thing. But for Teva and ZHP, all 2 of that would apply to the class group. 3 Q. I'm not sure I understood that. Can you 4 clarify what you mean? 5 A. So I'm not trying to -- I'm not trying to 6 represent that an issue with Mylan or an issue with 7 ZHP would apply to customers that -- a Mylan 8 product. However, if they're being sold the same 9 way and they're processed by Teva in the same way, 10 it would apply to all of the class group. 11 Q. And so similarly, you're not taking the 12 position that in observation with respect to or an 13 alleged noncompliance with CGMPs by Teva would 14 impact a different ANDA holder's product? 15 MR. DAVIS: Objection; incomplete 16 hypothetical. 17 But you can answer. 18 A. Okay. So we're talking about Teva versus 19 Torrent. If we're talking about that, okay, for 20 example, I'm not trying to imply what Teva did or 21 did not do would impact what Torrent did. 22 The point was these GMP violations apply 23 to the whole class, in terms of -- and all the 24 pills, everyone that received the product. 25 Q. All right. So let's take a look at</p>	<p style="text-align: right;">Page 172</p> <p>1 information request letter from August of 2018? 2 A. I'm not certain what information FDA had 3 or didn't have. I'm aware of the document you're 4 referring to. 5 Q. Okay. So you don't -- you don't know one 6 way or the other whether that was known to FDA prior 7 to that response in 2018? 8 A. So I -- it -- I'm not -- I'm not sure 9 how -- what relevance it has but, no, I'm not. 10 Q. Okay. And do you know whether that 11 information was known to any of the other defendants 12 in this litigation prior to 2018? 13 MR. DAVIS: Object to form, and 14 potentially calls for speculation. 15 But you can answer. 16 THE WITNESS: Okay. 17 A. I'm not aware of it, but they should have 18 been aware. So if you look at Section 105, this -- 19 this is the situation that caused the problem with 20 ZHP, they made a critical change. They 21 characterized it as critical, but when they made 22 their submission to the FDA, they called it a minor 23 change. And this goes back to 2011 and this is what 24 the defendants that used the ZH products should have 25 been aware of.</p>
<p style="text-align: right;">Page 171</p> <p>1 Paragraphs 104 through 106 in your report. 2 A. Okay. 3 Q. And here you are discussing observations 4 that were made by FDA in an establishment inspection 5 report in August of 2018. Correct? 6 A. I am. 7 Q. This was the 2018 inspection that you 8 were referencing earlier? 9 A. Yes. 10 Q. At the time that these observations were 11 made, Teva had already initiated its product recall 12 of valsartan-containing products which utilized 13 ZHP's API. Right? 14 A. I'm not -- I'm not certain of the time 15 frames. 16 Q. You don't know one way or the other 17 whether that recall was issued on July 16th of 2018? 18 A. I'm not certain when the recall was 19 actually initiated. I'm sure it's there someplace, 20 I just don't recall. 21 Q. Okay. Do you know whether -- do you know 22 whether FDA had any information about the presence 23 of NDMA exceeding 100 parts per million in 150 lots 24 of valsartan API from 2014 and 2015 prior to 25 receiving ZHP's response to the FDA's DMF</p>	<p style="text-align: right;">Page 173</p> <p>1 Q. Beginning at Paragraph 129 and continuing 2 through to Paragraph 143, you discuss certain -- or 3 you make certain representations with respect to 4 Mylan. Correct? 5 A. Right. 6 Q. You speak of risk assessments for 7 recovered solvents going back to -- 8 A. Which paragraph -- 9 Q. -- 2014? 10 A. -- are you referring to -- 11 MR. DAVIS: I believe that's 129. 12 THE WITNESS: Oh, 129. 13 Q. Yeah. 14 A. 129. Okay. 15 Q. And you reference that with respect to 16 Unit 8. Correct? 17 A. It is. That's what I reference here, 18 yes. 19 Q. But the 2020 EIR for Mylan cited these 20 observations in the context of Unit 7. Correct? 21 MR. DAVIS: Objection; 22 mischaracterizes the -- the document. 23 But you can answer. 24 A. So I'm not certain. So in terms of the 25 linkage that you're trying to make, I'm not certain.</p>

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1 We'd have to go back and look at the documents.
2 Q. Do you know whether at the time of this
3 EIR, do you know one way or the other whether any
4 particular defendant was purchasing valsartan API
5 from Mylan?
6 A. I don't know the time frames of when they
7 were purchasing.
8 MR. DAVIS: Which EIR are you
9 referring to, for the record?
10 Q. The EIR that you're referencing in
11 Paragraph 129.
12 MR. DAVIS: Is there --
13 THE WITNESS: Which --
14 MR. DAVIS: Is there a EIR that's
15 being referenced at 129?
16 Q. You're discussing observations from an
17 EIR in these paragraphs. Correct?
18 A. I didn't reference the EIR. I
19 referenced -- I have other references relative to
20 the statements that I made in 129.
21 Q. Do you know where those came from?
22 MR. DAVIS: Where -- objection;
23 vague.
24 A. So they came from References 61, 62, and
25 63.

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1 Q. Okay. So let me just ask it this way.
2 Are you aware of -- are you aware of a February 2020
3 EIR from Mylan?
4 A. February 2020?
5 Q. Yes.
6 A. I may be.
7 Q. Do you know whether any of the
8 observations you discuss with respect to Mylan in
9 your report come from that EIR?
10 A. If they do, I would have referenced them
11 in the document here.
12 Q. But as you sit here right now, you can't
13 specify which, if any, came from that EIR?
14 A. No, but I did -- I do reference where the
15 statements came from. And references 68, 69, and 70
16 all were from the 2020 EIR.
17 Q. Okay. And do you know which, if any, of
18 the defendants had currently active ANDAs for
19 products containing valsartan at the time of that
20 2020 EIR?
21 MR. DAVIS: Objection; vague.
22 Objection to the form.
23 You can answer.
24 A. So you're asking -- was the question --
25 maybe you want to rephrase the question?

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1 Q. Sure.
2 Do you know whether any of the defendants
3 had withdrawn their ANDAs with respect to products
4 containing valsartan at the time -- by the time of
5 that February 2020 EIR?
6 A. I'm not certain whether they did or not.
7 MR. DAVIS: Same -- same objections.
8 THE WITNESS: I'm sorry.
9 Q. Okay. Let's go to the section, starts at
10 the bottom of Page 28: Evidence common to the class
11 of defendant Teva's noncompliance with CGMPs.
12 Do you see that section?
13 A. I see that section, yes.
14 Q. And are you aware that on June 20th of
15 2018, Teva was informed of the preference --
16 presence of a previously known impurity? Previously
17 unknown impurity?
18 A. It's what?
[REDACTED]

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[REDACTED]

15 Q. As you sit here today, you don't know one
16 way or the other?
17 A. No, I'm not certain. No. Like, I want
18 to say again --
19 Q. Uh-huh.
20 A. -- the statements I have in this report
21 are examples, okay, I didn't review everything,
22 they're examples that it was a class that applied to
23 all products, so I didn't review every possible area
24 of concern.
[REDACTED]

14 Q. Are you aware that Teva announced a
15 recall of certain named valsartan products made with
16 ZHP's API on or about July 16th of 2018?

17 MR. DAVIS: Object to form.

18 You can answer.

19 A. I'm not aware -- well, I probably have
20 seen that, but I'm not particularly aware of it. It
21 wasn't pertinent to my report.

14 Q. Okay. Are you aware one way or the other
15 whether Teva announced a recall regarding specified
16 valsartan products containing Mylan's API on
17 November 25th of 2018?

18 MR. DAVIS: Object to form.

19 You can answer.

20 A. The same answer as before. Again, there
21 were a lot of documents around that period of time
22 that I may have seen, but they were not relevant to
23 my report.

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1 [REDACTED]
2 MR. DAVIS: Object -- I'm going to
3 object to the form.
4 You can answer.
5 A. They did, but they didn't get the
6 information that they needed.
7 Q. And these inspections were made according
8 to schedules established for audits of API
9 suppliers. Correct?
10 A. Well, I don't know that to be the case.
11 I don't know.
12 Q. You don't know one way or the other?
13 A. I don't know -- I don't know what --
14 you're asking the question whether they scheduled
15 the audits. I don't know.
16 But the issue, though, is they failed to
17 uncover the issues that existed.
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 Q. When you say "if it's here," you mean in
24 your report?
25 A. Yeah, in the report, yeah.

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1 Q. Do you know one way or another if it's
2 there?
3 A. I don't recall. I'd have to -- we'd have
4 to go back and look at all the references.
5 But the point is, if they had done the
6 audit the way I had suggested in 2011, they should
7 have been able to determine this critical change and
8 have investigated it.
9 Q. Are you aware of what a DMF is, a drug --
10 A. Yes.
11 Q. What do you understand DMF to refer to?
12 A. It's a Drug Master File.
13 Q. And what is a Drug Master File?
14 A. Drug Master File typically contains all
15 of the aspects relative to making whatever it is,
16 and it's by reference. And the ANDA or NDA will
17 reference the DMF as a reference. So if the FDA
18 does not approve a DMF, they'll approve the file
19 that references the DMF.
20 Q. Okay. What entity holds the DMF?
21 A. What do you mean, "what entity"?
22 Q. Would that be the entity that supplies
23 the API?
24 A. Well, the API manufacturer probably has
25 DMFs. I'm assuming Teva probably had DMFs.

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1 Q. You're referring, in your response, to
2 the ANDA will reference the DMF. What do you mean
3 there?
4 A. Okay. So when you're going to the
5 chemistry manufacturing control section of your ANDA
6 or NDA, you'll reference the DMF. And, typically,
7 that's what you would do. You don't actually
8 include that as part of the ANDA or the NDA because
9 it's by reference.
10 Q. Okay. So, for example, if a company like
11 Teva is obtaining API from a company like ZHP,
12 Teva's ANDA for the product that incorporates that
13 API would reference ZHP's DMF for that API.
14 Correct?
15 A. Well, so I'm not -- so Teva's got -- I
16 mean, ZHP has their own file, they have a DMF that
17 references their own file. So I'm not certain
18 whether the Teva ANDA would reference necessarily
19 the ZHP DMF. I don't know. I don't know whether
20 that would be the case or not, because I'm assuming
21 that Teva has their own DMF.
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
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21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

1 was in place between Teva by way of Actavis and ZHP?
2 A. I'm not certain whether I saw that or
3 not.
4 Q. Okay. So as you sit here today, you're
5 not aware, one way or the other, whether it requires
6 that ZHP notify Teva/Actavis in writing upon the
7 receipt of a regulatory inspection report?
8 A. So to answer that question, if there was
9 a quality agreement in place, that quality agreement
10 certainly should have spelled that out, okay, that
11 ZHP was required to do that. That would be a normal
12 component in a quality agreement between the two
13 entities.
14 Q. You didn't check for that, did you?
15 A. I don't think I saw it, but I'm saying in
16 that agreement, that's what they probably should
17 have had. I mean, it's a basic requirement for a
18 quality agreement.
19 Q. Okay. And as you sit here today, you
20 don't know, one way or the other, whether that was
21 in the quality agreement between Teva, Actavis, and
22 ZHP?
23 A. No.

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Page 202

[REDACTED]

Page 204

[REDACTED]

Page 203

[REDACTED]

Page 205

[REDACTED]

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1 Q. Would it be fair to say that the actions
2 that you undertook to determine whether Teva's
3 reaction to the major and minor observations was
4 sufficient was to review the documents that you have
5 identified in Exhibit A to your report?
6 MR. DAVIS: Object to form.
7 A. So I'm not sure which documents I review
8 there.
9 Q. But the documents that you reviewed in
10 connection with your report -- the documents that
11 you relied on in connection with your report are
12 listed in Exhibit A to your report?
13 A. That is correct.

[REDACTED]

215

[REDACTED]

Page 216

[REDACTED]

Page 217

[REDACTED]

<div data-bbox="344 291 849 315">Page 218</div> <div data-bbox="344 315 849 1039"><p>[REDACTED]</p></div>	<div data-bbox="849 291 1362 315"></div> <div data-bbox="849 315 1362 1039"><p>[REDACTED]</p></div>
<div data-bbox="344 1039 849 1064">Page 219</div> <div data-bbox="344 1064 849 1757"><p>[REDACTED]</p></div>	<div data-bbox="849 1039 1362 1064"></div> <div data-bbox="849 1064 1362 1757"><p>[REDACTED]</p></div>

<p>Page 222</p> <p>[REDACTED]</p>	<p>Page 224</p> <p>[REDACTED]</p>
<p>Page 223</p> <p>[REDACTED]</p>	<p>Page 225</p> <p>[REDACTED]</p>

<p style="text-align: right;">Page 226</p> <p>[REDACTED]</p>	<p style="text-align: right;">Page 228</p> <p>[REDACTED]</p>
<p style="text-align: right;">Page 227</p> <p>[REDACTED]</p>	<p style="text-align: right;">Page 229</p> <p>[REDACTED]</p> <p>12 Q. Okay.</p> <p>13 (Reporter admonishment.)</p> <p>[REDACTED]</p>

[illegible]

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[illegible]

Page 237

[illegible]

[illegible]

<p style="text-align: right;">Page 242</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>14 Q. So as you sit here today, you can't</p> <p>15 identify anything that implies that Teva does not</p> <p>16 adequate -- did not adequately conduct risk</p> <p>17 assessments per Q9, as you have described them?</p> <p>18 A. Because I've not necessarily looked at</p> <p>19 all the appropriate documents that I could have</p> <p>20 looked at.</p> <p>21 Q. Okay. And you have commented on change</p> <p>22 management systems in your Paragraph 49. Correct?</p> <p>23 A. 49?</p> <p>24 Yes.</p> <p>25 Q. Was there anything that you saw in any</p>	<p style="text-align: right;">Page 244</p> <p>1 MS. ISIDRO: All right. I have no</p> <p>2 further questions at this time, and I'll pass the</p> <p>3 witness to the next questioner.</p> <p>4 (Discussion off the written record.)</p> <p>5 THE VIDEOGRAPHER: Go off the record.</p> <p>6 (Break.)</p> <p>7 THE VIDEOGRAPHER: Back on the</p> <p>8 record. The time is 5:54 p.m. Back on the record.</p> <p>9 EXAMINATION</p> <p>10 BY MR. GOLDBERG:</p> <p>11 Q. Okay. Mr. Quick, my name is Seth</p> <p>12 Goldberg. I'm with the law firm Duane Morris, and</p> <p>13 we represent ZHP and a few of its affiliated</p> <p>14 companies.</p> <p>15 I'm going to ask you a few questions</p> <p>16 about your report, and in particular the ZHP section</p> <p>17 of your report, which starts on Page 20.</p> <p>18 MR. GOLDBERG: And I wanted to put</p> <p>19 up Exhibit -- well, make sure for the -- for the</p> <p>20 tech, this is Document No. 001 in our selection of</p> <p>21 documents.</p> <p>22 Q. And while he's doing that, Mr. Quick, is</p> <p>23 it -- when you look at this section of the ZHP</p> <p>24 section, is it fair to say that you --</p> <p>25 MR. DAVIS: We might have an issue</p>
<p style="text-align: right;">Page 243</p> <p>1 documents that you reviewed that implies that Teva</p> <p>2 does not have an adequate change management system,</p> <p>3 as you have described it?</p> <p>4 A. Again, I did not review that specific</p> <p>5 aspect of Teva to be able to make that</p> <p>6 determination.</p> <p>7 Q. Okay. And you have commented on process</p> <p>8 validation at your Paragraph 57. Correct?</p> <p>9 A. Yes.</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>17 Q. Okay. Anything else as to Teva with</p> <p>18 respect to process validation?</p> <p>19 A. Nothing. But that was just one example.</p> <p>20 There could be more examples, if I had other</p> <p>21 documents to review.</p> <p>22 Q. So if there are any other examples, it's</p> <p>23 not something that you reviewed?</p> <p>24 A. I just didn't review it, yes.</p> <p>25 Q. Okay. Okay.</p>	<p style="text-align: right;">Page 245</p> <p>1 here. Are you going to be able to read that, John?</p> <p>2 THE WITNESS: I cannot read it.</p> <p>3 (Discussion off the written record.)</p> <p>4 (Exhibit 19 was marked.)</p> <p>5 Q. This is the 2018 EIR report. Are you</p> <p>6 familiar with this document?</p> <p>7 A. This is the ZHP?</p> <p>8 Q. Correct.</p> <p>9 A. Okay.</p> <p>10 Q. Okay. You cite to this document a number</p> <p>11 of times in this section of the ZHP your opinions</p> <p>12 regarding ZHP. Do you see that? Why don't you flip</p> <p>13 through your report.</p> <p>14 A. I see that.</p> <p>15 Q. And most of your footnote cites refer to</p> <p>16 this document.</p> <p>17 MR. DAVIS: Objection.</p> <p>18 Q. Do you see that?</p> <p>19 A. Yes, I do see that. Some of them do,</p> <p>20 you're correct.</p> <p>21 Q. Okay. What do you understand this</p> <p>22 document to be?</p> <p>23 A. This is the Establishment and Inspection</p> <p>24 Report written by the FDA investigator that</p> <p>25 inspected the ZHP facility in 2018.</p>

<p style="text-align: right;">Page 246</p> <p>1 Q. And this document, if you look at the 2 very back, it's signed and dated -- this is on 3 Page 974, 58 of 58 in the PDF -- it was signed and 4 dated by two investigators on August 20th, 2018. Do 5 you see that? 6 A. I see that. 7 Q. Okay. Did you review any ZHP 8 communications with the FDA dated after August 20th, 9 2018? 10 A. I may have. I don't recall. 11 Q. Well, I don't see any cited in your 12 report, so did you or didn't you? 13 A. If it's not cited in my report, I didn't. 14 Q. Okay. What's a "warning letter 15 closeout"? 16 A. Warning letter closeout would be when the 17 FDA has reviewed whatever has been done relative to 18 the warning letter to begin, they close out the 19 warning letter. 20 Q. Did you review the warning letter 21 closeout that the FDA issued for ZHP related to this 22 EIR? 23 A. I may have seen that. 24 Q. Well, I just asked you if you looked at 25 any document after August 20th, 2018, and you said</p>	<p style="text-align: right;">Page 248</p> <p>1 the document? 2 A. I answered your question. I said -- 3 MR. DAVIS: Asked and answered. 4 Q. Why didn't you include it in your report? 5 A. It wasn't relevant to my report. 6 MR. DAVIS: Also, it was issued three 7 days before he signed his report. 8 (Exhibit 20 was marked.) 9 Q. Why wouldn't the FDA closeout letter be 10 relevant to your report? 11 A. What I cited in my report were examples 12 of CGMP deficiencies that occurred during the period 13 that I reviewed, and this occurred years after. 14 MR. DAVIS: Hey, Seth, I'm noticing 15 there is not a Bates stamp on this document. Is 16 this a document that ZHP has produced in this case? 17 (No audible response.) 18 Q. Did you review any of the observation 19 responses, the specific observation responses that 20 ZHP provided to the FDA in connection with this EIR? 21 A. The same applies to this. I may have 22 seen some of those documents. There were a lot of 23 documents that were provided. This document -- 24 those documents are not relevant to what my report 25 was about.</p>
<p style="text-align: right;">Page 247</p> <p>1 you didn't. 2 A. No, I didn't -- 3 MR. DAVIS: Well, hang on. Hang on, 4 Mr. Goldberg. You asked if he reviewed any 5 communications with FDA after 2018. 6 MR. GOLDBERG: Yeah, so -- 7 MR. DAVIS: I'm not sure a warning 8 letter -- a warning letter closeout would qualify. 9 MR. GOLDBERG: Well -- 10 A. I'll tell you what I said. I'll tell you 11 what I said, is that I may have reviewed some 12 documents. I didn't refer to those documents in my 13 report. 14 (Discussion off the written record.) 15 Q. Document No. 16. Do you know what this 16 document is, sir? 17 A. I'm reading it. 18 (Pause.) 19 It appears to be the closeout to the 20 warning letter. 21 Q. Is this the first time you've seen this 22 document? 23 A. As I said before, I may have seen it at 24 some point. I'm not sure whether I saw it or not. 25 Q. Yes or no, is this the first time you saw</p>	<p style="text-align: right;">Page 249</p> <p>1 Q. When you say "there were a lot of 2 documents provided," could you give us a sense of 3 What does that mean? Who provided them? What are 4 you talking about? 5 MR. DAVIS: Hang on, Seth. 6 Objection; asked and answered. This is -- this was 7 covered at length this morning. I don't think each 8 defendant gets a bite at the same apple when it's 9 already been covered once. 10 MR. GOLDBERG: This wasn't covered 11 this morning. 12 MR. DAVIS: It was. It was, Seth. 13 It was covered this morning. 14 MR. GOLDBERG: I'm not going to waste 15 time. 16 Q. Which ZHP documents, other than the ones 17 you've identified in Exhibit A, were provided? 18 A. The documents that I reviewed are the 19 ones that are in the -- in my report. 20 Q. Okay. So you didn't review the closeout 21 letter, because that wasn't in your report. Right? 22 MR. DAVIS: Well, hang on, Seth. I 23 asked you a question. 24 MR. GOLDBERG: No, no, no. 25 MR. DAVIS: Has ZHP produced this</p>

<p style="text-align: right;">Page 250</p> <p>1 document?</p> <p>2</p> <p>3 MR. GOLDBERG: Excuse me. Counsel,</p> <p>4 Counsel, the witness just answered a question, and</p> <p>5 I'm following up on that particular answer. That's</p> <p>6 it. There is no reason for you to be speaking.</p> <p>7 MR. DAVIS: Okay. You can answer the</p> <p>8 question, Mr. Quick.</p> <p>9 A. I did not review this document relative</p> <p>10 to my report.</p> <p>11 Q. And you didn't review any of the other</p> <p>12 communications ZHP had with the FDA between the date</p> <p>13 of the EIR and the closeout letter, because if you</p> <p>14 had, you would have identified them in your report.</p> <p>15 Right?</p> <p>16 A. I would have -- that's correct, I would</p> <p>17 have identified them.</p> <p>18 Q. Looking at Paragraph 105 of your</p> <p>19 report -- I'm sorry -- 104 of your report. You say</p> <p>20 that: The FDA observed that ZHP failed to conduct a</p> <p>21 formal risk assessment.</p> <p>22 MR. GOLDBERG: You could pull that</p> <p>23 document down that's up there.</p> <p>24 MR. DAVIS: I'm going to -- now that</p> <p>25 you've pulled it down, to the extent that's not been</p>	<p style="text-align: right;">Page 252</p> <p>1 clear. You only reviewed what's on Exhibit A.</p> <p>2 Right?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. So did you do -- did anything in</p> <p>5 Exhibit A -- if you look at that list, did you do</p> <p>6 anything to independently verify whether ZHP</p> <p>7 conducted a formal risk assessment?</p> <p>8 MR. DAVIS: Object to form.</p> <p>9 You can answer.</p> <p>10 A. So my role was to come up -- was to</p> <p>11 identify example -- examples of CH -- of CGMP</p> <p>12 deficiencies that might apply to the entire class,</p> <p>13 and not -- it was not exhaustive.</p> <p>14 That may be part of a later scope in this</p> <p>15 process, but that's -- I did not do an independent</p> <p>16 review of any other aspects of the ZHP EIR.</p> <p>17 Q. Okay. So the answer to my question is,</p> <p>18 no, you didn't do any independent assessment of</p> <p>19 whether or not ZHP did a formal risk assessment.</p> <p>20 Right?</p> <p>21 MR. DAVIS: Objection. He's already</p> <p>22 given his answer.</p> <p>23 Q. Sir, are you going to answer my question?</p> <p>24 A. The answer --</p> <p>25 Q. The answer is no.</p>
<p style="text-align: right;">Page 251</p> <p>1 produced to us, I would request that be produced</p> <p>2 with a Bates stamp.</p> <p>3 Q. Sir, did you -- do you need me to repeat</p> <p>4 my question or --</p> <p>5 A. What was the question, please?</p> <p>6 Q. -- maybe I interrupted. So let me turn</p> <p>7 your attention to 104. You say: The FDA observed</p> <p>8 that ZHP failed to conduct a formal risk assessment</p> <p>9 for the at-issue valsartan API manufacturing change.</p> <p>10 Do you see that?</p> <p>11 A. I see it.</p> <p>12 Q. Okay. And you cite to the 2018 EIR that</p> <p>13 we looked at. Right?</p> <p>14 A. That's correct.</p> <p>15 Q. Did you do anything to independently</p> <p>16 assess whether ZHP conducted a formal risk</p> <p>17 assessment, or are you just taking what the FDA is</p> <p>18 saying and putting that into your report?</p> <p>19 A. I reviewed the documents that were</p> <p>20 provided. I reviewed the FDA EIR. Obviously, I was</p> <p>21 not on-site at ZHP to verify any of these documents,</p> <p>22 and so that's where this -- that's where this came</p> <p>23 from.</p> <p>24 Q. Which documents? You said you "reviewed</p> <p>25 the documents provided," and I just want to be</p>	<p style="text-align: right;">Page 253</p> <p>1 A. I told you no before.</p> <p>2 Q. Okay. Where in the FDA regulations is</p> <p>3 the phrase "formal risk assessment" defined?</p> <p>4 A. So I address that in my report. There</p> <p>5 are numerous places.</p> <p>6 (Pause.)</p> <p>7 So FDA addresses this in Q9. They also</p> <p>8 address it in the guidance "Control of Nitrosamine</p> <p>9 Impurities in Human Drugs." And I reference that as</p> <p>10 Footnote 17. And they've addressed very</p> <p>11 specifically the amount of risk assessment.</p> <p>12 And if you look at my Page 11, you will</p> <p>13 see that. Risk assessments assess the risk in</p> <p>14 marketed products and products under approved and</p> <p>15 pending applications. Risk assessments should be</p> <p>16 conducted in a timely manner based on the</p> <p>17 prioritization of drugs. Manufacturers do not need</p> <p>18 to submit risk assessment documents to the agency,</p> <p>19 but they should retain these documents so they</p> <p>20 are -- should be available if requested.</p> <p>21 So that's where FDA cites this.</p> <p>22 Q. Does the FDA define with specificity the</p> <p>23 requirements of a risk assessment?</p> <p>24 A. They may. I'm just not aware offhand</p> <p>25 where that might be.</p>

<p style="text-align: right;">Page 254</p> <p>1 Q. The information you cited are not 2 specific requirements of a risk assessment. Right? 3 MR. DAVIS: Objection. 4 A. So what -- what are you referring to? 5 Q. Let me ask a different question. Can we 6 pull up Exhibit Document No. 17. 7 MR. DAVIS: For the record, this is 8 Exhibit 21. Is that right? 9 MR. GOLDBERG: Correct. This should 10 be Exhibit 21. 11 (Exhibit 21 was marked.) 12 Q. Do you see what the document is, sir? 13 A. I do. I do. 14 Q. What is the document? 15 A. It's quality risk management, Q9. 16 Q. And this is the document you just 17 referred to a minute ago when you said the FDA talks 18 about risk assessment in Q9. Right? 19 A. That's right. 20 Q. Okay. Could you turn to Page 6 of this 21 document? 22 A. I don't have the document in front of me. 23 MR. DAVIS: Yeah, you're going to 24 have to hand control over to him. 25 I'm going to place just a procedural</p>	<p style="text-align: right;">Page 256</p> <p>1 Do you see that? 2 A. I see that. 3 Q. Okay. And then if you go past that list, 4 it says: It might be appropriate to adapt these 5 tools for use in specific areas pertaining to drug 6 substance and drug product quality. 7 It goes on to say: Combined use provides 8 flexibility that can facilitate the application and 9 quality of risk management principals. The degree 10 of rigor and formality of quality risk assessment 11 should reflect available knowledge and be 12 commensurate with the complexity and/or criticality 13 of the issue to be addressed. 14 You agree that the FDA does not restrict 15 to a specific list of components how a risk 16 assessment should be conducted? 17 MR. DAVIS: Object to form. 18 You can answer. 19 A. That's generally correct. 20 Q. And that the FDA envisions that there 21 needs to be some flexibility in this process and 22 that it may be done in different ways depending on 23 the circumstances? 24 MR. DAVIS: Object to form. 25 You can answer.</p>
<p style="text-align: right;">Page 255</p> <p>1 objection on the record that he's not even able to 2 review the entire document when it's presented to 3 him. 4 Q. Sir, I'm turning your attention to Page 6 5 of Q9, which is a document you just referenced. 6 And, actually, if you look at the bottom of Page 5, 7 if you could turn to that, you'll see it says: Risk 8 management methodology. 9 And why don't you take a second to review 10 paragraph -- this section, risk management 11 methodology, if you need to. 12 A. (Pause.) 13 Okay. 14 Q. Okay. And if you look at Page 6 -- and 15 I'll just read this in the second paragraph. It 16 says -- 17 MR. DAVIS: Can you enhance the image 18 so that he can actually see it? 19 MR. GOLDBERG: Again, I'm not -- I 20 can't -- maybe the tech can. 21 MR. NOVAK: You just have to tell me 22 what you're reading, so I know what you're reading 23 from. 24 Q. It's a sentence that says: Below is a 25 nonexhaustive list of some of these tools.</p>	<p style="text-align: right;">Page 257</p> <p>1 A. It can be done in different forms. 2 Q. This document doesn't refer to a defined, 3 quote, formal risk assessment, does it? 4 A. Well, I haven't read the entire -- if you 5 want me to spend the time to read the document, I 6 would. 7 Q. Well, this Section 5 does not. Correct? 8 MR. DAVIS: Again, I'm going to state 9 my procedural objection that you're not even giving 10 him the opportunity to look at anything other than 11 what you've highlighted. 12 Q. Do you agree? 13 A. Based on what I'm seeing here, yes. 14 Q. Okay. What is your support for the 15 conclusion that ZHP did not file -- follow its own 16 standard management procedure? 17 MR. DAVIS: Object to form. 18 You can answer. 19 A. So we need to pull up Footnote 40. 20 (Exhibit 22 was marked.) 21 Q. Document No. 3. That's Footnote -- 22 that's the document at Footnote 40, sir. 23 Do you want to show me what you're 24 claiming is the support that ZHP did not follow its 25 own SMP?</p>

<p style="text-align: right;">Page 258</p> <p>1 MR. DAVIS: I object to that, Seth.</p> <p>2 He's not even able to control the document to show</p> <p>3 you.</p> <p>4 Q. Well, your footnote says Page 11 of 17.</p> <p>5 A. Oh, 11, yes.</p> <p>6 (Discussion off the written record.)</p> <p>7 MR. DAVIS: For the record, counsel</p> <p>8 has highlighted the top two paragraphs, it appears,</p> <p>9 of Page 11 of this document.</p> <p>10 Why don't you let counsel know when</p> <p>11 you've read that and then you want counsel to</p> <p>12 highlight the bottom portion of the document next.</p> <p>13 A. Yeah, why don't you highlight? Go ahead.</p> <p>14 You can move on.</p> <p>15 (Pause.)</p> <p>16 This appears to be a different version of</p> <p>17 the document than I have seen.</p> <p>18 Q. Sir, this is the document you cited,</p> <p>19 ZHP0000417.</p> <p>20 A. I'm just saying it appears to be --</p> <p>21 Q. It goes on to --</p> <p>22 (Simultaneous speaking.)</p> <p>23 A. I'm just saying it appears to be a</p> <p>24 different document.</p> <p>25 Q. You're not seeing support for your</p>	<p style="text-align: right;">Page 260</p> <p>1 A. This document needs to be reviewed in the</p> <p>2 context of what ZHP actually did. And what they</p> <p>3 actually did was do a series of check the boxes,</p> <p>4 which I saw that document. If we look at that</p> <p>5 document, you would see it. And the FDA also</p> <p>6 referenced that in their inspection when they were</p> <p>7 at ZHP and it's referenced in the 2018 EIR.</p> <p>8 Q. Did you review ZHP's response to that</p> <p>9 particular part of the EIR?</p> <p>10 A. We've already been through that and I</p> <p>11 told you I did not review the responses.</p> <p>12 This is in the total context of --</p> <p>13 MR. DAVIS: There's no question</p> <p>14 pending.</p> <p>15 Q. Other than what the FDA said in the EIR,</p> <p>16 did you review any particular document that supports</p> <p>17 this conclusion at Paragraph 108 --</p> <p>18 A. As I said --</p> <p>19 Q. -- in your report?</p> <p>20 A. -- as I said, I reviewed the actual risk</p> <p>21 assessment document that they actually did, which</p> <p>22 the FDA cited. I reviewed that document. It is a</p> <p>23 series of check the boxes.</p> <p>24 (Reporter admonishment.)</p> <p>25 Q. Document No. 2 in our list. 2A is the</p>
<p style="text-align: right;">Page 259</p> <p>1 conclusion on this page. Right?</p> <p>2 MR. DAVIS: Object in the way it's</p> <p>3 presented to the witness in piecemeal fashion, where</p> <p>4 he's not even able to read the entire page in one</p> <p>5 read. If you want, we can go off the record. I can</p> <p>6 print that document and we can start with it.</p> <p>7 Q. Am I correct, sir, that you're not seeing</p> <p>8 on Page 11 the support for this opinion?</p> <p>9 A. Well, we need to look at it as what they</p> <p>10 actually did. And I think the issue was what they</p> <p>11 actually did was simply checking boxes. And I think</p> <p>12 the FDA referenced that in the EIR. And I also saw</p> <p>13 that particular risk assessment document and I</p> <p>14 agreed with them.</p> <p>15 Q. So the answer to my -- to my question is,</p> <p>16 yes, this doesn't support your conclusion?</p> <p>17 MR. DAVIS: Objection; totally</p> <p>18 mischaracterizes his testimony.</p> <p>19 A. That's not what I said.</p> <p>20 Q. I asked you, am I correct that Page 11</p> <p>21 doesn't support the language in Paragraph 108 that</p> <p>22 you're citing?</p> <p>23 MR. DAVIS: Objection;</p> <p>24 mischaracterizes his testimony, and asked and</p> <p>25 answered now.</p>	<p style="text-align: right;">Page 261</p> <p>1 translation of this document.</p> <p>2 THE STENOGRAPHER: And don't forget</p> <p>3 to give these exhibit numbers if you want to mark</p> <p>4 them. I won't mention this again, but just for the</p> <p>5 record. Thanks.</p> <p>6 Q. We can mark this as Exhibit 23. I'm</p> <p>7 showing you the change request form document.</p> <p>8 (Exhibit 23 was marked.)</p> <p>9 Q. When you say this was a "check the box,"</p> <p>10 what do you mean by that?</p> <p>11 MR. DAVIS: For the record, the</p> <p>12 witness -- the type font in here is like 6.</p> <p>13 I object to this procedure of doing</p> <p>14 this. Like you're asking him very specific</p> <p>15 questions about documents and not letting him</p> <p>16 actually look at the document.</p> <p>17 MR. GOLDBERG: Don't you have the</p> <p>18 electronic version of the document? Isn't that how</p> <p>19 this works?</p> <p>20 MR. DAVIS: Well, look, I can't pull</p> <p>21 it up right on command, Seth.</p> <p>22 (Simultaneous speaking.)</p> <p>23 MR. GOLDBERG: You can access the</p> <p>24 electronic version of the document.</p> <p>25 MR. DAVIS: I don't know what</p>

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1 exhibits you're going to mark.

2 MR. GOLDBERG: Well, no, but when the

3 court reporter puts them up, Mr. Quick should be

4 able to review them.

5 MR. DAVIS: Yeah. He's looking --

6 MR. GOLDBERG: That's how we've done

7 that in the past.

8 MR. DAVIS: Well, let me explain to

9 you, Seth. He's about 30 feet away from the TV and

10 he's looking on an iPad. And unless you blow up the

11 document, he can't read the text. I can't read the

12 text. And he's not able to page through the

13 document to actually give it a good review. You're

14 just, you know, highlighting the portions you want

15 to show him. I think this is an improper procedure

16 for doing this.

17 MR. GOLDBERG: Well, these are

18 documents that he relied on to issue his expert

19 opinion and --

20 MR. DAVIS: Well, you have a

21 mechanism to hand control over to the witness.

22 MR. GOLDBERG: He has the documents

23 there.

24 MR. DAVIS: You want to hand control

25 to the witness so he can actually page through the

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1 document himself.

2 (Discussion off the written record.)

3 MR. GOLDBERG: Let's go off the

4 record.

5 THE VIDEOGRAPHER: Off the record at

6 6:26 p.m.

7 (Break.)

8 THE VIDEOGRAPHER: We're back on the

9 record at 6:42 p.m.

10 Q. Mr. Quick, I'm -- I'm looking at

11 Paragraph 108 of your report. You say: The failure

12 to conduct the necessary and comprehensive risk

13 assessment to a critical manufacturing change was in

14 violation of ZHP's own risk man- -- management

15 procedure.

16 And you cite to this document, Page 11 of

17 17. What are you -- what are you citing this

18 document for?

19 A. I'm looking at the document.

20 (Pause.)

21 It may have actually been Page 12 or --

22 let's see. Is it 12? Yeah. The format of risk

23 management includes special systematic and

24 nonspecial, nonsystematic for change control,

25 customer complaint investigation, deviation

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1 investigation.

2 It goes on about the type of -- the way

3 it should be formatted.

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 Q. Other than the EIR and this document that

14 we've marked as Exhibit 22, did you review anything

15 else from the 2010, '11, '12 time frame when this

16 critical change or change control was happening to

17 independently determine whether ZHP followed its own

18 SOPs?

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

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1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 MR. GOLDBERG: Can you pull up

6 Document No. 20, please?

7 (Exhibit 24 was marked.)

8 (Discussion off the written record.)

9 MR. DAVIS: For the record, the

10 witness has Exhibit 24 on a laptop.

11 Q. Do you have it up, sir?

12 A. I do.

13 Q. Okay. Can you please -- have you seen

14 this document before?

15 A. I'm not sure whether I have or not.

16 Q. Well, this document isn't listed in

17 Exhibit A. So can we agree that you haven't

18 reviewed this document before?

19 A. If it's not in Exhibit A, I probably have

20 not reviewed it.

21 Q. Okay. This is the change control system

22 SMP. Do you see that?

23 A. Yes.

24 Q. Do you see Paragraph 1 of the document

25 refers to the -- explains the purpose?

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1 A. I do. I see that.
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]
 5 [REDACTED]
 6 [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 [REDACTED]
 10 Do you see that?
 11 A. I do.
 12 Q. And if you can scroll down, in the page
 13 ending 148, and you'll see the numbers 6, 6.1. This
 14 is the procedure page. Correct?
 15 A. Okay.
 16 Q. You -- you --
 17 A. It's taking time to get there because
 18 it's got to refresh as I go down the pages.
 19 Okay. I see Page 10.
 20 Q. You've done nothing to independently
 21 determine whether ZHP satisfied the SOPs on this
 22 Page 6 -- 6 -- on this Page 148. Correct?
 23 MR. DAVIS: Object to form.
 24 You can answer.
 25 A. Well, since I haven't had the chance to

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1 review it, then I haven't had the chance to evaluate
 2 it.
 3 Q. So the answer is, yes, you haven't done
 4 anything to independently assess whether ZHP
 5 satisfied its internal SMPs?
 6 MR. DAVIS: Objection; asked and
 7 answered and to form.
 8 A. I haven't because it wasn't provided to
 9 be able to be reviewed. If I had the time to review
 10 this, maybe I could come to an opinion on that.
 11 Q. Turn to Paragraph -- you can pull that
 12 document down -- Paragraph 111 of your report. Did
 13 you -- did you review an org chart for the ZHP
 14 Tranon (phonetic) facility?
 15 A. I don't recall having reviewed it.
 16 Q. Well, again, it's not listed in
 17 Exhibit A, so you'll agree you didn't review one.
 18 Right?
 19 A. Right. If it's not there, I probably
 20 didn't.
 21 Q. Well, wait a second. You keep qualifying
 22 these answers and we're here at a deposition to be
 23 specific, sir, you're an expert witness. Okay.
 24 We're going to be specific about this instead of
 25 probables and I don't recall.

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1 MR. DAVIS: Seth.
 2 Q. If it's not in Exhibit A --
 3 MR. GOLDBERG: Hang on.
 4 Q. If it's not in Exhibit A, you didn't
 5 review it. Right?
 6 MR. DAVIS: Objection;
 7 mischaracterizes the report, mischaracterizes the
 8 responses to the notice of deposition.
 9 MR. GOLDBERG: We don't need -- we
 10 don't need a speaking objection.
 11 MR. DAVIS: No, I'm not --
 12 Q. If it's not in Exhibit A -- if it's not
 13 in Exhibit A, you didn't review it. Right?
 14 MR. DAVIS: Objection; facts not in
 15 record, mischaracterizes his responses to the
 16 notice, and mischaracterizes his testimony and asked
 17 and answered.
 18 Q. I'm going to ask it again, sir. You
 19 agree that you didn't review it because if you did
 20 it would be in Exhibit A. Right?
 21 MR. DAVIS: Last -- last answer and
 22 then you got to move on, Seth.
 23 You can --
 24 A. I -- I didn't review it.
 25 Q. Your Section 111 says: That the head of

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1 quality assurance -- I -- maybe you can -- what is
 2 your -- what is the point of your Paragraph 111?
 3 [REDACTED]
 4 [REDACTED]
 5 [REDACTED]
 6 [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 [REDACTED]
 10 [REDACTED]
 11 [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]
 16 [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 Q. Did you read -- did you read the entire
 20 deposition transcripts for these witnesses?
 21 A. No, I did not read the entire
 22 depositions -- depositions.
 23 Q. How did you identify specific excerpts
 24 then to rely on?
 25 MR. DAVIS: Objection to form.

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1 You can answer.
2 THE WITNESS: Okay.
3 A. I was provided with particular sections
4 from the law firm that took the depositions.
5 MR. GOLDBERG: Could you pull up
6 exhibit -- sorry -- Document No. 24 which we'll mark
7 as Exhibit 25, I believe.
8 THE WITNESS: I'll try to get back
9 there.
10 (Exhibit 25 was marked.)
11 Q. Okay. Do you have that --
12 A. No.
13 Q. -- testimony in front of you?
14 A. I do not.
15 Okay. It's in front of me.
16 Q. And your criticism in Paragraph 111, is
17 that Ms. Ge, the head of quality assurance was --
18 wasn't specific enough, wasn't certain enough about
19 whether the technology department provides a risk
20 assessment report. That's your criticism?
21 A. No, it's not. Sorry.
22 MR. DAVIS: Objection;
23 mischaracterizes the report and the testimony, both
24 his testimony --
25 Q. What is --

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1 MR. DAVIS: -- and Ms. Ge's
2 testimony.
3 Q. What is your criticism?
4 A. Okay. Normally, I would've expected the
5 quality function to be handling risk assessments.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 Q. Did the FDA note that in its EIR?
14 MR. DAVIS: Objection -- no to that?
15 Okay. No objection, you can answer.
16 A. If we go back to what the FDA said which
17 I had before.
18 So the FDA noted during the 2018
19 inspection that ZHP's quality risk management and
20 standard management procedure did not clearly
21 delineate which risk managements and methods and/or
22 tools should be used. And so they had problems with
23 the risk assessment. Regardless of whether FDA did,
24 I -- I agree that there was a problem.
25 But the real -- the real point here,

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6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
5 MR. DAVIS: We're getting close to
6 7 o'clock.
7 Q. Is it your opinion -- is it your opinion
8 that the technology department should not have a
9 role in the risk assessment?
10 A. No, I didn't say that and that's not my
11 opinion.
12 Q. And would it -- is it your opinion that
13 the quality assurance shouldn't have oversight of
14 the risk assessment from a GMP standpoint?
15 A. Well, I didn't say that either.
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 MR. DAVIS: Seth, we're at 7 o'clock
20 now, I believe.
21 MR. GOLDBERG: Okay. Let me just get
22 to the end of this line of questioning. I know
23 somebody needs to leave. So let me just get to the
24 end of this specific questioning.
25 MR. DAVIS: You've got two minutes to


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1 wrap it up because our court reporter, we've got to
2 respect the fact that she has another obligation.
3 (Discussion off the written record.)
4 MR. GOLDBERG: It's okay. We can go
5 off the record now.
6 THE VIDEOGRAPHER: Off the record at
7 7:00 p m.
8 (Deposition adjourned at 7:00 p m.)
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1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE
4 IN RE: VALSARTAN, § MDL NO 2875
5 LOSARTAN, AND §
6 IRBESARTAN PRODUCTS § HONORABLE ROBERT B KUGLER
7 LIABILITY LITIGATION § DISTRICT COURT JUDGE
8
9 REPORTER'S CERTIFICATION
10 DEPOSITION OF JOHN L QUICK
11 TAKEN JANUARY 27, 2022
12 I, TAMARA CHAPMAN, Certified Shorthand Reporter in
13 and for the State of Texas, hereby certify to the
14 following:
15 That the witness, JOHN L QUICK, was duly sworn by
16 the officer and that the transcript of the oral
17 deposition is a true record of the testimony given
18 by the witness;
19 That the original deposition was delivered to
20 NILDA ISIDRO;
21 That a copy of this certificate was served on all
22 parties and/or the witness shown herein on
23 _____
24 I further certify that pursuant to FRCP No
25 30(f)(i) that the signature of the deponent:
_____ was requested by the deponent or a party before
the completion of the deposition and that the
signature is to be returned within 30 days from date

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1 of receipt of the transcript. If returned, the
2 attached Changes and Signature Page contains any
3 changes and the reasons therefor;
4 was not requested by the deponent or a party
5 before the completion of the deposition.
6 I further certify that I am neither counsel for,
7 related to, nor employed by any of the parties in
8 the action in which this proceeding was taken, and
9 further that I am not financially or otherwise
10 interested in the outcome of the action.
11 Certified to by me this 9th day of February, 2022.
12
13
14
15 
16 Tamara Chapman, CSR, RPR-CRR
17 CSR NO. 7248; Expiration Date: 12-31-22
18 Veritext Legal Solutions
19 Firm Registration No. 571
20 300 Throckmorton Street, Suite 1600 Fort
21 Worth, Texas 76102
22 800-336-4000
23
24
25

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1 John R. Davis
2 jdavis@slackdavis.com
3 February 9, 2022
4 RE: In Re: Valsartan, Losartan, Et Al
5 1/27/2022, John Quick (#5025079)
6 The above-referenced transcript is available for
7 review.
8 Within the applicable timeframe, the witness should
9 read the testimony to verify its accuracy. If there are
10 any changes, the witness should note those with the
11 reason, on the attached Errata Sheet.
12 The witness should sign the Acknowledgment of
13 Deponent and Errata and return to the deposing attorney.
14 Copies should be sent to all counsel, and to Veritext at
15 erratas-cs@veritext.com
16
17 Return completed errata within 30 days from
18 receipt of testimony.
19 If the witness fails to do so within the time
20 allotted, the transcript may be used as if signed.
21
22 Yours,
23 Veritext Legal Solutions
24
25

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1 In Re: Valsartan, Losartan, Et Al
2 John Quick (#5025079)
3 E R R A T A S H E E T
4 PAGE _____ LINE _____ CHANGE _____
5 _____
6 REASON _____
7 PAGE _____ LINE _____ CHANGE _____
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9 REASON _____
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15 REASON _____
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17 _____
18 REASON _____
19 PAGE _____ LINE _____ CHANGE _____
20 _____
21 REASON _____
22 _____
23 _____
24 John Quick Date _____
25

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1 In Re: Valsartan, Losartan, Et Al

2 John Quick (#5025079)

3 ACKNOWLEDGEMENT OF DEPONENT

4 I, John Quick, do hereby declare that I

5 have read the foregoing transcript, I have made any

6 corrections, additions, or changes I deemed necessary as

7 noted above to be appended hereto, and that the same is

8 a true, correct and complete transcript of the testimony

9 given by me.

10

11 _____

12 John Quick Date

13 *If notary is required

14 SUBSCRIBED AND SWORN TO BEFORE ME THIS

15 _____ DAY OF _____, 20____.

16

17

18

19 _____

NOTARY PUBLIC

20

21

22

23

24

25

71 (Page 278)

[& - 19103]

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Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Page 1

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 IN RE: VALSARTAN, § MDL NO. 2875
5 LOSARTAN, AND §
6 IRBESARTAN PRODUCTS § HONORABLE ROBERT B.
7 LIABILITY LITIGATION § KUGLER
8 DISTRICT COURT JUDGE

9
10 ORAL AND VIDEOTAPED DEPOSITION OF
11 JOHN QUICK
12 JANUARY 28, 2022

13 ORAL AND VIDEOTAPED DEPOSITION OF JOHN QUICK,
14 produced as a witness at the instance of the Defendants
15 and duly sworn, was taken in the above styled and
16 numbered cause on January 28, 2022 from 8:00 a.m. to
17 12:09 p.m., before JANALYN ELKINS, CSR, in and for the
18 State of Texas, reported by computerized stenotype
19 machine, at the offices of Slack Davis Sanger, LLP, 6001
20 Bold Ruler Way, Suite 100, Austin, Texas, pursuant to
21 the Federal Rules of Civil Procedure and any provisions
22 stated on the record herein.
23
24
25

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES</p> <p>2</p> <p>3 FOR THE PLAINTIFF(S):</p> <p>4 John R Davis</p> <p>5 SLACK DAVIS SANGER, LLP</p> <p>6 6001 Bold Ruler Way, Suite 100</p> <p>7 Austin, Texas 78746</p> <p>8 512-795-8686</p> <p>9 jdavis@slackdavis.com</p> <p>10</p> <p>11 Layne Hilton</p> <p>12 Conlee S Whiteley</p> <p>13 David J Stanoch</p> <p>14 KANNER & WHITELEY, L L C</p> <p>15 701 Camp Street</p> <p>16 New Orleans, Louisiana 70130</p> <p>17 504-524-5777</p> <p>18 l hilton@kanner-law.com</p> <p>19 c whiteley@kanner-law.com</p> <p>20 d stanoch@kanner-law.com</p> <p>21</p> <p>22 Ruben Honik</p> <p>23 HONIK LLC</p> <p>24 1515 Market Street, Suite 1100</p> <p>25 Philadelphia, Pennsylvania 19102</p> <p>26 267-435-1300</p> <p>27 ruben@honiklaw.co</p> <p>28</p> <p>29 FOR PLAINTIFF MSP RECOVERY CLAIMS, SERIES, LLC:</p> <p>30 Charlie Whorton</p> <p>31 RIVERO MESTRE, LLP</p> <p>32 2525 Ponce De Leon Boulevard, Suite 1000</p> <p>33 Miami, Florida 33134</p> <p>34 305-445-2500</p> <p>35 cwhorton@riveromestre.com</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES</p> <p>2 (Continued)</p> <p>3</p> <p>4 FOR ZHEJIANG HUAHAI PHARMACEUTICAL, CO , LTD , SOLCO</p> <p>5 HEALTHCARE U S , LLC, AND PRINSTON PHARMACEUTICAL, INC :</p> <p>6 Seth Goldberg</p> <p>7 DUANE MORRIS, LLP</p> <p>8 30 South 17th Street</p> <p>9 Philadelphia, Pennsylvania 19103</p> <p>10 215-979-1175</p> <p>11 sagoldberg@duanemorris.com</p> <p>12</p> <p>13 Coleen W Hill</p> <p>14 DUANE MORRIS, LLP</p> <p>15 30 South 17th Street</p> <p>16 Philadelphia, Pennsylvania 19103</p> <p>17 215-979-1164</p> <p>18 cwhill@duanemorris.com</p> <p>19</p> <p>20 FOR HUMANA INC & HUMANA PHARMACY, INC :</p> <p>21 Megan A Zmick</p> <p>22 FALKENBERG IVES, LLP</p> <p>23 230 W Monroe, Suite 2220</p> <p>24 Chicago, Illinois 60606</p> <p>25 312-566-4808</p> <p>26 maz@falkenbergives.com</p> <p>27</p> <p>28 FOR AUROBINDO PHARMA LTD :</p> <p>29 Steven N Hunchuck</p> <p>30 John Gisleson</p> <p>31 MORGAN LEWIS</p> <p>32 One Oxford Centre, 32nd Floor</p> <p>33 Pittsburgh, Pennsylvania 15219</p> <p>34 412-560-3300</p> <p>35 steven.hunchuck@morganlewis.com</p> <p>36 john.gisleson@morganlewis.com</p>
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<p style="text-align: right;">Page 7</p> <p>1 APPEARANCES (Continued)</p> <p>2</p> <p>3 FOR PFIZER INC , VALEANT PHARMACEUTICALS INTERNATIONAL, 4 INC , BAUSCH & LOMB INCORPORATED, AND ATON PHARMA, INC : Liza M Walsh 5 Christine I Gannon WALSH PIZZIZI O'REILLY FALANGA, LLP 6 Three Gateway Center 100 Mulberry Street, 15th Floor 7 Newark, New Jersey 07102 973-757-1100 lwalsh@walsh.law cgannon@walsh.com</p> <p>8</p> <p>9</p> <p>10 FOR CVS HEALTH CO : Kara Kapke 11 BARNES & THORNBURG, LLP 11 S Meridian Street 12 Indianapolis, Indiana 46204 317-231-6491 kara.kapke@btlaw.com</p> <p>13</p> <p>14</p> <p>15 FOR H J HARKINS CO , INC : Geoffrey M Coan 16 HINSHAW & CULBERTSON, LLP 53 State Street, 27th Floor 17 Boston, Massachusetts 02109 617-213-7000 gcoan@hinshawlaw.com</p> <p>18</p> <p>19</p> <p>20 FOR OPTUM, INC & OPTUMRX: Shevon D B Rockett 21 DORSEY & WHITNEY, LLP 51 West 52nd Street 22 New York, New York 10019 212-415-9357 rockett.shevon@dorsey.com</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 9</p> <p>1 INDEX PAGE</p> <p>2</p> <p>3 Appearances 2</p> <p>4 Examination by Mr Goldberg 10</p> <p>5 Examination by Mr Stoy 44</p> <p>6 Examination by Mr Hunchuck 78</p> <p>7 Examination by Mr Abraham 100</p> <p>8 Examination by Ms Nagle 126</p> <p>9 Further Examination by Ms Ididro 143</p> <p>10 Examination by Mr Davis 147</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p>1 EXHIBITS</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11 NO DESCRIPTION PAGE</p> <p>12 Exhibit 26 Min Li Deposition 25</p> <p>13 Exhibit 27 Jucai Ge Deposition 32</p> <p>14 Exhibit 28 Jun Du Deposition 37</p> <p>15 Exhibit 29 Linda Lin Deposition 39</p> <p>16 Exhibit 30 FDA Observation 106</p> <p>17 Exhibit 31 FDA Observation 106</p> <p>18 Exhibit 32 Objections and Responses To Notice of Deposition 137</p> <p>19 Exhibit 33 Production Documents and Deposition Transcripts Responsive to Request No 6 139</p> <p>20</p> <p>21 Exhibit 34 Flash Drive 146</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

<p style="text-align: right;">Page 10</p> <p>1 (Witness previously sworn)</p> <p>2 VIDEOGRAPHER: Here begins the continuation</p> <p>3 of the deposition of John Quick. Today's date is</p> <p>4 January 28, 2022. We are on the record at 8:12 a.m.</p> <p>5 EXAMINATION</p> <p>6 Q. (BY MR. GOLDBERG) Good morning, Mr. Quick.</p> <p>7 A. Good morning.</p> <p>8 Q. We're going to pick up with the questioning</p> <p>9 regarding the ZHP portion of your report that we were</p> <p>10 discussing yesterday. Just before we get started, we</p> <p>11 sent your -- we sent plaintiff's counsel some documents</p> <p>12 earlier this morning. Did you look at those documents?</p> <p>13 A. I have not seen those documents.</p> <p>14 Q. Okay. I want to ask you, in your report from</p> <p>15 Pages 20 to 25, you've identified five areas that in</p> <p>16 your opinion ZHP's CGMP's were deficient. Am I correct?</p> <p>17 A. I'm not sure of five. Probably -- if you say</p> <p>18 it's five, it probably is five. I didn't count the</p> <p>19 number here.</p> <p>20 Q. Well, if you just look at the headings there,</p> <p>21 there are five headings. These are -- these are five</p> <p>22 general areas.</p> <p>23 A. Okay.</p> <p>24 Q. So are these the five -- are these five</p> <p>25 areas -- I guess are these five areas you are claiming</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. Let's look at the first one, the failure to</p> <p>2 conduct the risk assessment. This was based on -- it</p> <p>3 looks like Footnote 35, the August 2018 FDA EIR that we</p> <p>4 looked at yesterday, right?</p> <p>5 MR. DAVIS: Objection to form. You can</p> <p>6 answer.</p> <p>7 THE WITNESS: It was also based on my</p> <p>8 review of what they actually did, the documents.</p> <p>9 Q. (BY MR. GOLDBERG) Okay. Which -- which</p> <p>10 documents again? Because I'm looking at Page 21 of your</p> <p>11 report. So you're citing to the EIR.</p> <p>12 MR. DAVIS: Object to form. Is there a</p> <p>13 question there?</p> <p>14 Q. (BY MR. GOLDBERG) Yes. Which documents other</p> <p>15 than the EIR are you relying on for this point that ZHP</p> <p>16 failed to conduct the risk assessment?</p> <p>17 A. Well, let's see, which document was that? I</p> <p>18 don't recall which document it was. It was the document</p> <p>19 where they had yes/no answers. And it was also, I</p> <p>20 think, the same document you had yesterday.</p> <p>21 Q. Okay. So that -- that's the EIR is one and</p> <p>22 then the change form, which was Exhibit 23, is what we</p> <p>23 looked at yesterday, right?</p> <p>24 A. Well, I'm not sure which exhibit that was.</p> <p>25 Q. Well, that's the one that I showed you</p>
<p style="text-align: right;">Page 11</p> <p>1 ZHP's CGMP's were deficient?</p> <p>2 A. These are examples of the deficiencies. These</p> <p>3 are not necessarily all the deficiencies, but these are</p> <p>4 examples.</p> <p>5 Q. Okay. How did you come up with these examples?</p> <p>6 A. As I was reviewing documents, I picked</p> <p>7 examples. I didn't necessarily have any system to pick</p> <p>8 these particular examples, but they were examples of the</p> <p>9 CGMB deficiencies that I saw.</p> <p>10 Q. Did plaintiff's counsel identify these for you?</p> <p>11 A. No.</p> <p>12 Q. Did you discuss these five with plaintiff's</p> <p>13 counsel?</p> <p>14 MR. DAVIS: I'm going to -- you can answer</p> <p>15 the question, but I think we've agreed that</p> <p>16 communications between the parties and the experts are</p> <p>17 not subject to disclosure.</p> <p>18 THE WITNESS: Well, we've discussed the</p> <p>19 report. I don't know that we discussed these specific</p> <p>20 ones.</p> <p>21 Q. (BY MR. GOLDBERG) Okay. Can we go through --</p> <p>22 I just want to -- I just want to confirm the basis for</p> <p>23 each of these because you said that they were based on</p> <p>24 the documents that you reviewed, right?</p> <p>25 A. Right.</p>	<p style="text-align: right;">Page 13</p> <p>1 yesterday that you just referred to. I'm just telling</p> <p>2 you it's Exhibit 23.</p> <p>3 A. Okay.</p> <p>4 Q. So if that's the case, those are the two</p> <p>5 documents that form the basis of this opinion, right?</p> <p>6 A. Well, there are -- there were a number of ZHP</p> <p>7 documents that I looked at. So I'm not sure that those</p> <p>8 were the only ones.</p> <p>9 Q. Well, I'm asking you when you look at this</p> <p>10 section, Paragraphs 104 through 109 at least on Pages 20</p> <p>11 and 21, you're relying on the EIR and that Exhibit 23,</p> <p>12 right?</p> <p>13 MR. DAVIS: Object to form. Also</p> <p>14 mischaracterizes the report.</p> <p>15 You can answer.</p> <p>16 Q. (BY MR. GOLDBERG) That was a question.</p> <p>17 A. Okay. These are the footnotes I had for those</p> <p>18 sections. There are a number of other ZHP documents</p> <p>19 that are in the attachment that I did, in fact, review,</p> <p>20 and they may include some of those which are not</p> <p>21 included as footnotes. So I'm not saying that these</p> <p>22 were the only documents that are in the footnotes. I</p> <p>23 reviewed the ZHP documents that are in the attachment --</p> <p>24 I think it's Attachment A.</p> <p>25 Q. Which of the documents on Exhibit A support</p>

<p style="text-align: right;">Page 14</p> <p>1 your conclusions in Paragraphs 104 through 109?</p> <p>2 A. Well, we'd have to go back and pull each of</p> <p>3 these documents up and look through them because I'm not</p> <p>4 sure which ones are which here because we just reference</p> <p>5 the actual ZHP number.</p> <p>6 Q. Okay. So when I look at Exhibit A, the</p> <p>7 materials related to ZHP, all right, it looks like they</p> <p>8 sort of follow in order of your opinions. So the first</p> <p>9 ZHP document you cite at Footnote 35 is the first</p> <p>10 document here on Exhibit A, 7917. Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. Okay. And then the next document you cite at</p> <p>13 Footnote 36, and now we're -- we're tracking along this,</p> <p>14 Footnote 36 is cited at Paragraph 105. That appears as</p> <p>15 the second document in Exhibit A. Do you see that?</p> <p>16 A. I do see that.</p> <p>17 Q. Okay. And then Footnotes 37 through 4 --</p> <p>18 through 39, they -- they go back to that EIR, right?</p> <p>19 A. Through 30 -- 39, yes.</p> <p>20 Q. Yeah. And then 40 and 41, they appear in</p> <p>21 consecutive order on Exhibit A. Okay? And 40 is what</p> <p>22 we introduced as Exhibit 23 yesterday. All right? Do</p> <p>23 you agree with that?</p> <p>24 A. I'd have to go back and verify, but it sounds</p> <p>25 to be accurate.</p>	<p style="text-align: right;">Page 16</p> <p>1 discuss that, we need to pull the document up and take a</p> <p>2 look at it.</p> <p>3 Q. (BY MR. GOLDBERG) The next document on the</p> <p>4 list which -- in Exhibit A which ends in 24, is also an</p> <p>5 email related to -- to unknown peaks. And you cite this</p> <p>6 later in your report at Footnote 45. Again, I'm just</p> <p>7 trying to identify the documents that you relied on for</p> <p>8 this section of your report. And it's okay if you said</p> <p>9 I -- I relied on the EIR and the change control and I</p> <p>10 relied on the unknown peak emails for that section of my</p> <p>11 report. I'm just trying to understand where -- where</p> <p>12 you're -- where you're drawing your lines.</p> <p>13 MR. DAVIS: Object to form and object to</p> <p>14 the use of the term "documents" as vague. He's relied</p> <p>15 on other things as well.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: So I relied on a number of</p> <p>18 these documents for that opinion.</p> <p>19 Q. (BY MR. GOLDBERG) If you relied on the unknown</p> <p>20 peak related emails for this testimony, why didn't you</p> <p>21 cite it here?</p> <p>22 A. I didn't necessarily put each of the -- a</p> <p>23 footnote for each of the documents I reviewed for each</p> <p>24 section. I indicated some of those. And as I've</p> <p>25 indicated earlier, the points -- the examples in my</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Okay. And 41 we introduced as Exhibit 22</p> <p>2 yesterday, which was ZHP's SMPs related to the change</p> <p>3 control. Do you accept that representation?</p> <p>4 A. I'd have to go back and check it, but it sounds</p> <p>5 to be correct.</p> <p>6 Q. Okay. Then -- so -- so these are the documents</p> <p>7 you're citing on -- from 104 to 109. When we look at</p> <p>8 Exhibit A, the next document after -- after what is 41,</p> <p>9 which is 950, the next document on Exhibit A ends</p> <p>10 with 896. Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. Okay. I'll represent to you that that's an</p> <p>13 email that relates to the unknown peaks that you discuss</p> <p>14 later in your report. Okay? Did -- did you rely on</p> <p>15 that in connection with your opinions from 104 to 109?</p> <p>16 MR. DAVIS: Object to form.</p> <p>17 THE WITNESS: As I indicated a minute or</p> <p>18 two ago, I looked at the ZHP documents in totality to</p> <p>19 rely on my opinions. And so there may have been</p> <p>20 sections in those -- other documents that I relied upon.</p> <p>21 Q. (BY MR. GOLDBERG) What does the email</p> <p>22 with un -- related to unknown peaks have to do with your</p> <p>23 opinions with respect to the change control?</p> <p>24 MR. DAVIS: Object to form.</p> <p>25 THE WITNESS: Well, if we really want to</p>	<p style="text-align: right;">Page 17</p> <p>1 report are just examples. There are other deficiencies</p> <p>2 that I had seen as I was reviewing the ZHP documents</p> <p>3 that are not necessarily in my report because these are</p> <p>4 just examples that applied to the entire class.</p> <p>5 Q. The -- let's -- let's go on. So at least</p> <p>6 you'll agree that for 104 through 108, the only</p> <p>7 documents you cited as support for those paragraphs are</p> <p>8 the EIR and the two change process documents we</p> <p>9 discussed?</p> <p>10 A. What I would say is is those are the documents</p> <p>11 I footnoted.</p> <p>12 Q. Okay. And the -- if you go -- if you go on to</p> <p>13 Paragraphs 110 through 112, and we'll -- this was an</p> <p>14 area we discussed a little bit yesterday. This is that</p> <p>15 area where you're talking about the confusion that --</p> <p>16 the apparent confusion, as you put it, between these</p> <p>17 employees about the risk assessment?</p> <p>18 MR. DAVIS: Object --</p> <p>19 Q. (BY MR. GOLDBERG) And there you're relying on</p> <p>20 the testimony -- the portions of testimony that you cite</p> <p>21 here, right?</p> <p>22 MR. DAVIS: Object to form. Object to the</p> <p>23 mischaracterization of his testimony yesterday.</p> <p>24 You can answer.</p> <p>25 THE WITNESS: Well, that in addition into</p>

<p style="text-align: right;">Page 18</p> <p>1 the other documents which -- which were cited in the EIR</p> <p>2 as well. So just not those.</p> <p>3 Q. (BY MR. GOLDBERG) Did you -- and then when we</p> <p>4 go down to the unknown peaks, then you cite to -- you</p> <p>5 cite to the four emails in the unknown at Footnote 44</p> <p>6 and 45, right?</p> <p>7 A. Those are the footnotes I cite in the report,</p> <p>8 yes.</p> <p>9 Q. Okay. In -- on Page 23 when you are talking</p> <p>10 about this heading ZHP's Failure to Adequately Validate</p> <p>11 the Valsartan Process Change, for these paragraphs,</p> <p>12 you're again citing the EIR, right?</p> <p>13 A. Those are the -- those footnotes reference the</p> <p>14 EIR.</p> <p>15 Q. Did you look at any testimony related to -- in</p> <p>16 Paragraph 116, do you recall looking at any testimony in</p> <p>17 relation to your conclusion that's referenced in</p> <p>18 Paragraph 116?</p> <p>19 A. I may have. I was provided the full</p> <p>20 depositions for all of the individuals that were deposed</p> <p>21 from ZHP and Princeton. I did review all of those and</p> <p>22 there may have been other sections in there as well.</p> <p>23 Those are exhaustive documents.</p> <p>24 Q. I'm sorry. Your testimony today is that you</p> <p>25 read the full deposition transcripts?</p>	<p style="text-align: right;">Page 20</p> <p>1 somehow.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: No.</p> <p>4 Q. (BY MR. GOLDBERG) Are you changing your</p> <p>5 testimony?</p> <p>6 A. No, I am not changing that. I did not read the</p> <p>7 entire deposition. I skimmed through the deposition. I</p> <p>8 did not read the entire deposition. We're talking</p> <p>9 hundreds of pages in some cases. I skimmed through that</p> <p>10 for pertinent points.</p> <p>11 Q. I asked you how did you identify the specific</p> <p>12 excerpts you relied on and you said I was provided with</p> <p>13 particular sections from the law firm that took the</p> <p>14 depositions. Is that -- are you changing your</p> <p>15 testimony?</p> <p>16 MR. DAVIS: Object -- object to form.</p> <p>17 Object to the mischaracterization that he's changing his</p> <p>18 testimony.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: So I asked about specific</p> <p>21 sections, and I was directed to those sections by the</p> <p>22 law firm.</p> <p>23 Q. (BY MR. GOLDBERG) Did you try to determine</p> <p>24 whether any of the portions of testimony that</p> <p>25 plaintiff's counsel provided to you were contradicted by</p>
<p style="text-align: right;">Page 19</p> <p>1 A. No. That is not what I said. When I said I</p> <p>2 reviewed, I didn't necessarily review every single</p> <p>3 paragraph of those depositions. I skimmed through the</p> <p>4 depositions.</p> <p>5 Q. Okay. And yesterday you testified that</p> <p>6 plaintiff's counsel provided you portions of testimony,</p> <p>7 right?</p> <p>8 A. No.</p> <p>9 MR. DAVIS: Object to form. And object to</p> <p>10 the mischaracterization of his testimony yesterday.</p> <p>11 THE WITNESS: No, that is not what I said.</p> <p>12 I was -- I was provided the full depositions for each of</p> <p>13 those individuals.</p> <p>14 Q. (BY MR. GOLDBERG) Mr. Quick, I just --</p> <p>15 yesterday I asked you how did you identify specific</p> <p>16 excerpts in the testimony. Well, first of all, I</p> <p>17 said -- I asked you did you read the entire deposition</p> <p>18 transcripts for these witnesses and you answered, no, I</p> <p>19 did not read the entire depositions.</p> <p>20 MR. DAVIS: Is there a question there?</p> <p>21 Q. (BY MR. GOLDBERG) Are you -- are you changing</p> <p>22 that testimony now?</p> <p>23 A. No.</p> <p>24 MR. DAVIS: Object to form. Object to the</p> <p>25 mischaracterization that his testimony is changing</p>	<p style="text-align: right;">Page 21</p> <p>1 other portions of testimony?</p> <p>2 MR. DAVIS: Object to form. You can</p> <p>3 answer.</p> <p>4 THE WITNESS: No, I did not do that. As I</p> <p>5 indicated, I skimmed through the depositions. I didn't</p> <p>6 necessarily look for that particular situation as you</p> <p>7 are describing it.</p> <p>8 Q. (BY MR. GOLDBERG) If -- if there was testimony</p> <p>9 that contradicted portions of testimony that were</p> <p>10 highlighted for you by plaintiff's counsel, would you</p> <p>11 have wanted to know that in reaching your opinions?</p> <p>12 MR. DAVIS: Object to form. Object to the</p> <p>13 premise of the question.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: I don't think it was</p> <p>16 particularly relevant at the time. But if, in fact,</p> <p>17 those were -- you directed those to me, I could probably</p> <p>18 review those as potentially an update. But what -- what</p> <p>19 was stated in depositions I think was pretty clear.</p> <p>20 Q. (BY MR. GOLDBERG) What was stated in the</p> <p>21 portions of testimony that plaintiff's counsel provided</p> <p>22 to you was pretty clear, and that's your testimony?</p> <p>23 MR. DAVIS: Object to form. Object to the</p> <p>24 characterization that's underlying your question. You</p> <p>25 can answer.</p>

<p style="text-align: right;">Page 22</p> <p>1 THE WITNESS: No, that's not what I said. 2 What I said was I was provided the full depositions. I 3 asked for the relevant portions in the depositions were 4 and the attorneys provided me -- directed me to those 5 particular sections. I had the full entire deposition. 6 Q. (BY MR. GOLDBERG) Did you ever think -- did 7 you think that plaintiff's attorneys might -- might not 8 provide you the complete picture of the testimony when 9 they are providing you with what they think are the 10 relevant portions? 11 MR. DAVIS: Object to form. 12 You can answer. 13 THE WITNESS: So as I -- as I stated, I was 14 provided the full depositions. I skimmed through the 15 depositions. I was directed to specific areas. No, to 16 answer your question, I did not think that to be the 17 case. And as I also said -- as I have also said if this 18 were to proceed, I would probably do a more in-depth 19 review of the entire deposition. These depositions are 20 very lengthy. 21 Q. (BY MR. GOLDBERG) Let's pull up Exhibit 20 -- 22 25. 23 MR. DAVIS: Is this one of the documents, 24 Seth? 25 MR. GOLDBERG: This was actually an</p>	<p style="text-align: right;">Page 24</p> <p>5 Q. Okay. So is it -- is it your opinion when you 6 look at Lines 5 and 6 that Ms. Gi is unclear about who's 7 to provide a risk assessment report? 8 MR. DAVIS: Object to form and object to 9 the, you know, selective display of, you know, two pages 10 of a deposition transcript. 11 You can answer. 12 MR. GOLDBERG: Counsel -- Counsel, that's 13 speaking objection is completely inappropriate. And I'm 14 going to ask you now to just say objection to form. Say 15 vague. Okay. But you don't need to start to make 16 speeches. I'm asking -- I would like the question read 17 back and I would like an answer to the question. 18 (Requested question was read.) 19 MR. DAVIS: Same objections. 20 You can answer. 21 THE WITNESS: As I indicated in the report, 22 I still believe there was some confusion between those 23 two groups relative to the who was doing the risk 24 assessment, who was responsible for it. Even here she</p>
<p style="text-align: right;">Page 23</p> <p>1 exhibit we -- yes, you should have this. This was the 2 exhibit we -- we ended on yesterday. It was up 3 yesterday. 4 MR. DAVIS: This is -- oh, okay. All 5 right. 6 MR. GOLDBERG: This is Exhibit 25. This is 7 the testimony of Jucai Ge. 8 MR. DAVIS: One second, Seth. Let me hand 9 the document to the witness. Should we -- should we be 10 marking this or -- 11 MR. GOLDBERG: This marked was an -- this 12 was marked as an exhibit yesterday. 13 MR. DAVIS: Okay. Okay. 14 MR. GOLDBERG: This was marked as 15 Exhibit 25 yesterday. 16 MR. DAVIS: So the witness for the record 17 has Jucai Ge's deposition excerpt that was sent to us 18 this morning. 19 Q. (BY MR. GOLDBERG) And I would like you to turn 20 to Page 276 of the testimony. And I would just like you 21 to read Line 5 and 6. [REDACTED]</p>	<p style="text-align: right;">Page 25</p> <p>2 and normally, I would have expected the quality function 3 to have a more active role in the risk assessment. So I 4 still stand by the statements in the report. 5 MR. GOLDBERG: Okay. Can you turn -- can 6 we pull up Tab 20 -- Tab 25 which we'll mark as 7 Exhibit 26? 8 (Exhibit No. 26 was marked.) 9 MR. DAVIS: Which one is this? 10 MR. GOLDBERG: This is the testimony of Min 11 Li. 12 MR. DAVIS: For the record is -- is Jucai 13 Gi 25? 14 MR. GOLDBERG: Yes. 15 MR. DAVIS: Okay. 16 MR. GOLDBERG: And this, the testimony of 17 Min Li, will be Exhibit 26. 18 MR. DAVIS: Okay. For the record, I've 19 handed -- I've handed the witness Exhibit 26, which is a 20 two-page document. 21 THE REPORTER: Hold on. I need to mark it. 22 Q. (BY MR. GOLDBERG) Now, while we're doing that, 23 if you look at Paragraph 111 of your report, sir, you 24 say that Min Li, the head of the technology department, 25 would testify that it was actually Ms. Ge who would be,</p>

<p style="text-align: right;">Page 26</p> <p>1 quote, in a better position to discuss the problem of</p> <p>2 sodium nitrate quenching resulting in nitrosamines,</p> <p>3 right? That's what your report says, right?</p> <p>4 A. That's what the report says.</p> <p>5 Q. Okay. Now when you look at the testimony of</p> <p>6 Min Li on Page 107, he's asked, (Reading:) Well,</p> <p>7 whatever you want to call it, he was correct that the</p> <p>8 sodium nitrate quenching was creating nitrosamines which</p> <p>9 was a serious GMP problem, correct? And Mr. Li's answer</p> <p>10 is, (Reading:) In terms of a GMP, you know, Ms. Gi</p> <p>11 would be in a better position.</p> <p>12 So Mr. Li is being pretty clear that Ms. Gi</p> <p>13 is the person to turn to with respect to the GMP, right?</p> <p>14 MR. DAVIS: Object to form.</p> <p>15 THE WITNESS: I'm not sure what's different</p> <p>16 between what you're having me look at than what's in my</p> <p>17 report.</p> <p>18 Q. (BY MR. GOLDBERG) Well, your report takes out</p> <p>19 of context the phrase in a better position and says</p> <p>20 nothing about Mr. Li identifying Ms. Gi as the person to</p> <p>21 talk to with respect to GMP, does it?</p> <p>22 MR. DAVIS: Object to form. Object to the</p> <p>23 characterization of his report.</p> <p>24 THE WITNESS: So I still stand by the</p> <p>25 statements that I believe there was confusion between</p>	<p style="text-align: right;">Page 28</p> <p>1 THE WITNESS: Again, I'm not sure what</p> <p>2 you're asking me to agree to.</p> <p>3 Q. (BY MR. GOLDBERG) Let's read back the</p> <p>4 question.</p> <p>5 (Requested question was read.)</p> <p>6 MR. DAVIS: Restate my objections.</p> <p>7 You can answer.</p> <p>8 THE WITNESS: Well, if we're looking at</p> <p>9 this particular section of transcript, that does not say</p> <p>10 that.</p> <p>11 Q. (BY MR. GOLDBERG) It doesn't say in terms of a</p> <p>12 GMP Ms. Gi would be in a better position?</p> <p>13 A. No, it does say that.</p> <p>14 Q. But your report doesn't identify that, right?</p> <p>15 MR. DAVIS: Object to form.</p> <p>16 THE WITNESS: It does say that Ms. Gi would</p> <p>17 be in a better position to discuss the problem.</p> <p>18 Q. (BY MR. GOLDBERG) Your report doesn't say that</p> <p>19 Mr. Li identified Ms. Gi as the person who would be in a</p> <p>20 better position in terms of GMP, right?</p> <p>21 MR. DAVIS: Object to form.</p> <p>22 THE WITNESS: Well, if we're looking at the</p> <p>23 transcript, the transcript is not stating that. I'm</p> <p>24 not -- still I'm not sure what point you're trying to</p> <p>25 make. The point I made in my report was that there was</p>
<p style="text-align: right;">Page 27</p> <p>1 the individuals as to who was responsible and who was</p> <p>2 conducting the risk assessments.</p> <p>3 Q. (BY MR. GOLDBERG) So my -- the answer to my</p> <p>4 question is, you're correct, my report does not say that</p> <p>5 Mr. Li directed -- directed -- identified Ms. Gi as the</p> <p>6 person to talk to with respect to GMP, right?</p> <p>7 MR. DAVIS: Same objections.</p> <p>8 Q. (BY MR. GOLDBERG) Your report doesn't say</p> <p>9 that?</p> <p>10 A. Well, I'm not sure I understand exactly the</p> <p>11 point that you're making here.</p> <p>12 Q. Well -- okay. I want an answer to my question.</p> <p>13 MR. DAVIS: Is -- is -- is there another</p> <p>14 question?</p> <p>15 Q. (BY MR. GOLDBERG) I want an answer to that</p> <p>16 question. Your report --</p> <p>17 MR. DAVIS: He's asked for clarification,</p> <p>18 Seth.</p> <p>19 Q. (BY MR. GOLDBERG) Your report does not say</p> <p>20 that Ms. -- Mr. Li identified Ms. Gi as the person to</p> <p>21 talk to with respect to GMP even though that's what his</p> <p>22 testimony says, correct?</p> <p>23 MR. DAVIS: Object to form, object to the</p> <p>24 characterization.</p> <p>25 You can answer.</p>	<p style="text-align: right;">Page 29</p> <p>1 confusion between the two groups within the company as</p> <p>2 to who was responsible and who was conducting the risk</p> <p>3 assessment. That was the whole point out of that.</p> <p>4 Q. (BY MR. GOLDBERG) Okay. Well -- and the point</p> <p>5 of my question is, it doesn't seem like there's</p> <p>6 confusion. Mr. Li in his testimony is identifying</p> <p>7 Ms. Gi as the person who's in a better position with</p> <p>8 respect to GMP, correct?</p> <p>9 MR. DAVIS: Object to counsel's testifying.</p> <p>10 Object to form.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: Again, based on the documents</p> <p>13 I read, I do think that there was confusion between</p> <p>14 those parties.</p> <p>15 Q. (BY MR. GOLDBERG) Answer my question, sir.</p> <p>16 MR. DAVIS: He has answered your question,</p> <p>17 Seth.</p> <p>18 THE WITNESS: I just did.</p> <p>19 MR. GOLDBERG: Counsel -- Counsel, enough.</p> <p>20 MR. DAVIS: Objection, asked and answered.</p> <p>21 MR. GOLDBERG: You're interfering -- you're</p> <p>22 interfering with this testimony at this point. State</p> <p>23 your objection. That's it.</p> <p>24 MR. DAVIS: Objection, asked and answered.</p> <p>25 MR. GOLDBERG: I want an answer to my</p>

<p style="text-align: right;">Page 30</p> <p>1 question.</p> <p>2 Q. (BY MR. GOLDBERG) I would like an answer to my</p> <p>3 question.</p> <p>4 MR. DAVIS: You can answer it one more</p> <p>5 time. Do you even know what the question is?</p> <p>6 THE WITNESS: Do you want to reread the</p> <p>7 question?</p> <p>8 Q. (BY MR. GOLDBERG) Mr. Li identified --</p> <p>9 Mr. Li's testimony says that in terms of GMP, Ms. Gi</p> <p>10 would be in a better position with respect to the risk</p> <p>11 assessment, right?</p> <p>12 MR. DAVIS: Objection, asked and answered.</p> <p>13 Object to form.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: Okay. If you're asking if</p> <p>16 that particular sentence is in this transcript, the</p> <p>17 answer is, no, it is not.</p> <p>18 Q. (BY MR. GOLDBERG) Mr. Li says in terms of GMP</p> <p>19 Ms. Gi would be in a better position. You agree with</p> <p>20 that, right?</p> <p>21 A. Well, are you asking me to agree with my</p> <p>22 report?</p> <p>23 Q. I'm asking you to agree with what I just asked</p> <p>24 you, that Mr. Li's testimony says in terms of GMP Ms. Gi</p> <p>25 would be in a better position.</p>	<p style="text-align: right;">Page 32</p> <p>1 MR. GOLDBERG: No, this is --</p> <p>2 THE REPORTER: Jucai Gi.</p> <p>3 MR. GOLDBERG: This is -- yeah, that's</p> <p>4 right. Yeah, it's a mistype -- it's a typo on her name.</p> <p>5 It's Jucai Gi at least on this thing, volume 2.</p> <p>6 MR. DAVIS: Oh, I see. I'm handing the</p> <p>7 witness -- or I'm handing the court reporter to be</p> <p>8 marked Exhibit 27.</p> <p>9 (Exhibit No. 27 was marked.)</p> <p>10 Q. (BY MR. GOLDBERG) Okay. You have that</p> <p>11 document in front of you, sir?</p> <p>12 A. I do.</p> <p>13 Q. Okay. At Paragraph 114 of your report, you</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 Do you see that?</p> <p>20 A. I do see that.</p> <p>21 Q. This is one of the -- and then you cite to her</p> <p>22 testimony at Section 46. Do you see that, at</p> <p>23 Footnote 46?</p> <p>24 A. I do.</p> <p>25 Q. This is one of those portions of testimony that</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Yes, and that's what I said in my report.</p> <p>2 Q. That's not what you said in your report.</p> <p>3 That's the problem, sir. Your report leaves out the</p> <p>4 fact that Mr. Li identified Ms. Gi as being in a better</p> <p>5 position in terms of GMP.</p> <p>6 MR. DAVIS: Object to form.</p> <p>7 Q. (BY MR. GOLDBERG) Doesn't it?</p> <p>8 MR. DAVIS: Object to counsel's testifying.</p> <p>9 You can answer if there's a question there.</p> <p>10 THE WITNESS: Yes, I'm not really sure what</p> <p>11 you're trying to get here because my report indicates</p> <p>12 that Dr. Li would testify it was actually Ms. Gi would</p> <p>13 be in a better position to discuss the problem. That's</p> <p>14 what I said in my report. I'm not sure what's different</p> <p>15 between what I said in my report and what you just said.</p> <p>16 Q. (BY MR. GOLDBERG) Let's go on to Exhibit --</p> <p>17 this is Document 28. We'll mark this as Exhibit 27.</p> <p>18 MR. DAVIS: Is this --</p> <p>19 MR. GOLDBERG: This is the testimony --</p> <p>20 John, this is the testimony from Jucai Ge.</p> <p>21 MR. DAVIS: I thought this was previously</p> <p>22 marked, Seth. Is this not previously marked? Oh, is</p> <p>23 this a different excerpt?</p> <p>24 I have a -- I have an April 29th printed</p> <p>25 out, volume 3. Oh, Jucai Gi. Okay. I know --</p>	<p style="text-align: right;">Page 33</p> <p>1 counsel highlighted for you?</p> <p>2 MR. DAVIS: Object to form.</p> <p>3 THE WITNESS: As -- as I said before, I</p> <p>4 asked what sections that they could direct me to that</p> <p>5 might be relevant, and this is one of the sections that</p> <p>6 they directed me to.</p> <p>7 Q. (BY MR. GOLDBERG) Okay. Could you read for</p> <p>8 yourself Pages 169 of this testimony through 170? Just</p> <p>9 take a minute to do that.</p> <p>10 A. Okay.</p> <p>11 Q. Okay. When -- when you look at that testimony,</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 MR. DAVIS: Object to form.</p> <p>20 THE WITNESS: Well, I have no idea what she</p> <p>21 was actually thinking when she made these statements. I</p> <p>22 do not know.</p> <p>23 Q. (BY MR. GOLDBERG) That really doesn't answer</p> <p>24 my question.</p> <p>25 [REDACTED]</p>

<p style="text-align: right;">Page 34</p> <p>[REDACTED]</p> <p>8 A. Again --</p> <p>9 MR. DAVIS: Object to form.</p> <p>10 THE WITNESS: Again, as I indicated, I have</p> <p>11 no idea what she was thinking. I just considered this</p> <p>12 to be an appropriate analogy.</p> <p>13 Q. (BY MR. GOLDBERG) Okay. So you -- you -- you</p> <p>14 acknowledge it's an analogy, right?</p> <p>15 A. She obviously was trying to make an analogy.</p> <p>16 Q. Okay. It might not be a good analogy, right?</p> <p>17 A. I'm sorry. I missed that.</p> <p>18 Q. It might not have been a good analogy, right?</p> <p>19 A. It might not have been a good analogy, correct.</p> <p>[REDACTED]</p> <p>24 MR. DAVIS: Object to form.</p> <p>25 THE WITNESS: So you're asking me to try to</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. (BY MR. GOLDBERG) Okay. Let's turn to</p> <p>2 Page 1 -- I'm sorry, Page 23 of your report and I'm</p> <p>3 looking at Paragraph 116. You can pull down that</p> <p>4 testimony if you'd like. Paragraph 116.</p> <p>5 A. Okay.</p> <p>6 Q. You say, (Reading:) The real reason for making</p> <p>7 this critical change was not so much in reducing isomer</p> <p>8 conversion and increasing yield as had been stated, but</p> <p>9 rather to save money.</p> <p>10 And then you go on to quote the EIR which</p> <p>11 quotes -- the EIR quote -- says -- I'm sorry. Let me --</p> <p>12 let me ask that question differently.</p> <p>13 You quote the EIR which quotes a statement</p> <p>14 by Jun Du, the executive vice president of ZHP, correct?</p> <p>15 A. That is correct.</p> <p>16 Q. Okay. Did you look at Mr. Du's testimony about</p> <p>17 what he said with respect to this statement?</p> <p>18 A. I may have. But I was -- what I'm referencing</p> <p>19 here is what he told the FDA investigator.</p> <p>20 Q. Mr. Du's testimony is not listed as any of the</p> <p>21 materials you reviewed. So you didn't review his</p> <p>22 testimony?</p> <p>23 A. Right. If it's not listed here, then I did not</p> <p>24 review it.</p> <p>25 Q. Did you review any -- do -- do you recall</p>
<p style="text-align: right;">Page 35</p> <p>1 understand what she was thinking when she made this and</p> <p>2 I don't know.</p> <p>3 Q. (BY MR. GOLDBERG) Okay. So you don't know,</p> <p>4 but yet in your report you want to -- you reach some</p> <p>5 conclusion about what she's saying, right?</p> <p>6 MR. DAVIS: Object to form.</p> <p>7 THE WITNESS: Well, that's -- that's not</p> <p>8 what I said in 114.</p> <p>9 Q. (BY MR. GOLDBERG) Do you feel like in --</p> <p>10 in 114, did you fairly characterize Mrs. Gi's testimony</p> <p>11 on 169 and 170?</p> <p>12 A. I believe I did.</p> <p>[REDACTED]</p> <p>20 MR. DAVIS: Object to form. Objection,</p> <p>21 asked and answered.</p> <p>22 You can answer again.</p> <p>23 THE WITNESS: Again, I'll say as I said</p> <p>24 before, I have no idea what she was trying to accomplish</p> <p>25 when she made this statement in the deposition.</p>	<p style="text-align: right;">Page 37</p> <p>1 reviewing anybody's testimony as to this particular --</p> <p>2 this particular portion of the EIR that you're reporting</p> <p>3 from?</p> <p>4 A. Well, there are a number -- there are a number</p> <p>5 of transcripts that I was provided that I did -- as I</p> <p>6 indicated, I did review. I've not -- I have no idea</p> <p>7 whether I reviewed all of them -- exactly what I</p> <p>8 reviewed at this point. But the situation here relative</p> <p>9 to the statement was basically he was telling the FDA</p> <p>10 investigator that the real intent for making this change</p> <p>11 was to save money. That was the point of that</p> <p>12 Section 116.</p> <p>13 Q. Can we pull up document No. 31 in our list,</p> <p>14 which we'll mark as Exhibit 28?</p> <p>15 (Exhibit No. 28 was marked.)</p> <p>16 MR. DAVIS: For the record I'm handing the</p> <p>17 witness the May 28th Jun Du face page and one page of</p> <p>18 deposition testimony.</p> <p>19 Q. (BY MR. GOLDBERG) If you look, sir, Page 232</p> <p>20 of that testimony --</p> <p>21 MR. DAVIS: Seth, the court reporter has</p> <p>22 just marked it and handed it to the witness.</p> <p>23 Do you want to take a moment to review?</p> <p>24 THE WITNESS: Sure. Okay. I'm looking</p> <p>25 at 232.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. (BY MR. GOLDBERG) In 232 Mr. Du says, 2 (Reading:) I did not state that the cost reduction 3 would cause dominant well market share. 4 Do you see that? 5 A. I do see that. 6 Q. Okay. This answer on Page 232 -- let me go 7 back. 8 At 231 plaintiff's counsel was reading to 9 Mr. Du the exact language that you quote at Page 116 of 10 your report. Do you see that? 11 A. I do see that. 12 Q. Okay. And Mr. Du says, (Reading:) I do not 13 agree with that -- this statement here. I did not make 14 such an apology, and I do not understand why it was 15 written here. I did not state that the cost reduction 16 would cause dominant world market share. 17 Do you see that? 18 A. I do see that. 19 Q. Is this the first time you've seen that Mr. Du 20 denies making this statement that -- that you've put in 21 Section 116? 22 A. This is the first time I've seen that 23 statement, yes. 24 MR. GOLDBERG: Okay. Can we pull up 25 document No. 32, please? And we'll mark this as</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. Ms. Lin was the -- the head of regulatory at 2 ZHP. She was asked on Page 209, she was read that same 3 portion of the EIR that you cite in 116. Do you see 4 that? 5 A. I do see that. 6 Q. And she says, (Reading:) In my recollection I 7 do not recall Mr. Du saying this to the FDA. This is 8 not what I can recall. And second, based on my 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 Do you see that? 14 A. I do see that. 15 Q. Is this the first time you've seen testimony 16 from Ms. Lin that refutes the notion that Mr. Du said 17 what -- what you've quoted in Section 116 of your 18 report? 19 A. This is the first time I've read what -- what 20 you've just provided to me. 21 Q. Okay. I just want to ask you a few more 22 questions about your report. 23 Pages -- let's -- let's go to Section 4 in 24 your report, these -- these Paragraphs 117 through 126. 25 You rely on a 2010 email from Remonda Gergis, and this</p>
<p style="text-align: right;">Page 39</p> <p>1 Exhibit 29. 2 (Exhibit No. 29 was marked.) 3 MR. DAVIS: For the record, I'm handing the 4 court reporter to be marked the May 5th deposition face 5 page of Linda Lin and a couple of -- two pages of 6 deposition testimony. 7 Q. (BY MR. GOLDBERG) If you could look, sir, at 8 Pages 207, 208, 209, 210, I'll direct you to specific 9 portions, but... 10 MR. DAVIS: Do you want a few moments to 11 review since he's asking you to look at multiple pages? 12 THE WITNESS: Yes. 13 MR. DAVIS: Okay. 14 Q. (BY MR. GOLDBERG) And I'm going to ask you 15 about 207, 208, 209, 210. 16 MR. DAVIS: Okay. The witness is going to 17 read those pages. 18 THE WITNESS: Okay. 19 Q. (BY MR. GOLDBERG) Okay. On Page 208 -- well, 20 let's go down to 209. You see on 209, Ms. -- Ms. Lin -- 21 do you know who Linda Lin is? Do you know what her role 22 was at ZHP? 23 A. There are a number of individuals. I'd have to 24 go back and determine what specific role she had. There 25 are a number of individuals, so...</p>	<p style="text-align: right;">Page 41</p> <p>1 is at Paragraph 118 in the section entitled, "ZHP's 2 Failure to Adequately Train Quality Assurance." Am I 3 correct about that? 4 MR. DAVIS: Object to form. 5 THE WITNESS: Well -- well, 118 refers to 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 where I see that in Section 118. 12 Q. (BY MR. GOLDBERG) That's the -- that's the 13 words that you used. 14 A. I'm just -- 15 Q. The heading -- heading No. 4 says -- 16 A. Oh, okay. Okay. At the top, yes. But I 17 thought we were referring to Section 118. 18 Q. Well, I'm -- I'm looking at this section of 19 your report. But you're relying on this 2010 email when 20 you're talking about ZHP's -- in your view ZHP's failure 21 to adequately train quality assurance personnel, right? 22 MR. DAVIS: Object to form. 23 Mischaracterizes the report. 24 You can answer. 25 THE WITNESS: So I am relying upon what</p>

<p style="text-align: right;">Page 42</p> <p>1 Ms. Gergis, if I'm pronouncing her name correctly,</p> <p>2 stated in that email, yes.</p> <p>3 Q. (BY MR. GOLDBERG) And you're relying on it for</p> <p>4 what purpose?</p> <p>5 A. Well, to show that ZH -- ZHP was an operation</p> <p>6 out of control.</p> <p>7 Q. And her email is in 2010, right?</p> <p>8 A. Yes.</p> <p>9 Q. Is it your opinion that her email related to</p> <p>10 ZHP's operations between 2010 and 2018?</p> <p>11 A. I'm relying on what she said relative to what</p> <p>12 she saw in 2010.</p> <p>13 Q. Okay. So your opinion is about ZHP in 2010,</p> <p>14 right?</p> <p>15 MR. DAVIS: Object to form. Object to the</p> <p>16 mischaracterization.</p> <p>17 THE WITNESS: I'm relying on the fact of</p> <p>18 what she found when she was there in 2010. I believe</p> <p>19 there's other statements. But I think she came back a</p> <p>20 year or two later and had similar situations.</p> <p>21 Q. (BY MR. GOLDBERG) Did you -- if you look at</p> <p>22 Paragraph 119, you cite another inspection by Ms. Gergis</p> <p>23 in 2014, right?</p> <p>24 A. I do.</p> <p>25 Q. Okay. And what do you rely on that inspection</p>	<p style="text-align: right;">Page 44</p> <p>1 MR. GOLDBERG: Okay. I -- I'm going to</p> <p>2 conclude my examination now.</p> <p>3 THE WITNESS: Take a break?</p> <p>4 MR. DAVIS: Do you want to take a break?</p> <p>5 THE WITNESS: Can we take a break?</p> <p>6 MR. DAVIS: Yeah. The witness has</p> <p>7 indicated he wants to take a five-minute break. We've</p> <p>8 been going for about an hour any ways.</p> <p>9 VIDEOGRAPHER: Off the record 9:09 a.m.</p> <p>10 (Brief recess.)</p> <p>11 VIDEOGRAPHER: We are back on the record</p> <p>12 at 9:18 a.m.</p> <p>13 EXAMINATION</p> <p>14 Q. (BY MR. STOY) Morning, Mr. Quick.</p> <p>15 A. Good morning.</p> <p>16 Q. My name is Frank Stoy, and I represent the</p> <p>17 Mylan defendants in this litigation. I'm going to ask</p> <p>18 you some questions this morning about the portion of</p> <p>19 your report and your opinions that pertain to Mylan. Do</p> <p>20 you understand that?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Now I want to direct your attention</p> <p>23 first to Page 36 of your report and specifically to</p> <p>24 Paragraph 191. Let me know when you're there.</p> <p>25 A. I am.</p>
<p style="text-align: right;">Page 43</p> <p>1 for?</p> <p>2 MR. DAVIS: Object to form.</p> <p>3 THE WITNESS: Well, I'm relying on the fact</p> <p>4 that she came back in 2014 to do another inspection and</p> <p>5 she observed similar CGMP issues.</p> <p>6 Q. (BY MR. GOLDBERG) Did you identify any</p> <p>7 instance between 2010 and 2014, the dates of these</p> <p>8 documents, where the FDA found CGMP issues at ZHP?</p> <p>9 A. You know, as I've said a number of times, this</p> <p>10 report only has examples of the CGMP examples that I</p> <p>11 found. It's not all exhaustive. So the answer is I</p> <p>12 have not looked at every possible document. I looked at</p> <p>13 specific examples relative to CGMP deficiencies that</p> <p>14 applied to the class.</p> <p>15 Q. So the answer to my question is no?</p> <p>16 MR. DAVIS: Object to the</p> <p>17 mischaracterization.</p> <p>18 THE WITNESS: I did not reference any --</p> <p>19 any inspections in the period of time that you're</p> <p>20 talking about in my report.</p> <p>21 Q. (BY MR. GOLDBERG) Were you aware that the --</p> <p>22 that the FDA did not find any objectionable CGMP</p> <p>23 conditions at ZHP between 2010 and 2015?</p> <p>24 A. I did not review those documents relative to</p> <p>25 this report.</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Okay. I see in the back part of that paragraph</p> <p>2 where you say, (Reading:) The corporate quality</p> <p>3 assurance deficiencies described herein are the type of</p> <p>4 quality assurance activities that would have impacted</p> <p>5 each of the manufacturer defendants valsartan products</p> <p>6 equally and in the same manner.</p> <p>7 Did I read that correctly?</p> <p>8 A. You did.</p> <p>9 Q. Okay. I want to ask you about this statement</p> <p>10 as it pertains to my client. Okay?</p> <p>11 So earlier in your deposition, I -- I heard</p> <p>12 you testify about a 2011 process change by ZHP; is that</p> <p>13 correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And -- and is it your understanding or your</p> <p>16 belief that that process change lead to the presence of</p> <p>17 the nitrosamine impurity in ZHP's API?</p> <p>18 A. It would appear to be the case. My comment</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 Q. Are you aware that ZHP used a different process</p> <p>24 to manufacture valsartan API than my client, Mylan?</p> <p>25 A. I'd have to go back and review those documents.</p>

<p style="text-align: right;">Page 46</p> <p>1 Q. So is your testimony that you're not sure as</p> <p>2 you sit here today whether Mylan and ZHP used the same</p> <p>3 process to manufacture valsartan API?</p> <p>4 A. Again, I reviewed a lot of documents. We could</p> <p>5 go look at those documents if we wanted to. I'm just</p> <p>6 not certain at this point today this morning.</p> <p>7 Q. Have you reviewed documents that reflect the</p> <p>8 different processes used by the different manufacturers?</p> <p>9 A. As I said before on this report, this report</p> <p>10 only attempted to identify specific -- certain examples</p> <p>11 to demonstrate the overall CGMP deficiencies that are</p> <p>12 pertained to the class, and I have not reviewed</p> <p>13 everything.</p> <p>14 Q. So as you sit here today, you don't know</p> <p>15 whether any of your observations regarding ZHP's</p> <p>16 manufacturing process would apply to Mylan or not,</p> <p>17 correct?</p> <p>18 MR. DAVIS: Objection. Outside of the</p> <p>19 scope. Asked and answered and he's not a process</p> <p>20 chemist.</p> <p>21 But you can try.</p> <p>22 THE WITNESS: So as I've said, I've</p> <p>23 reviewed the various documents and I put the CGMP</p> <p>24 deficiencies as I've seen them. You're asking a very</p> <p>25 specific question which I may or may not have seen, so</p>	<p style="text-align: right;">Page 48</p> <p>1 impurity that was detected in 2018, correct?</p> <p>2 A. Well, I don't know, so I can't say correct</p> <p>3 because I don't know. I'd have to go back and look at</p> <p>4 the documents. Again, as I said I did not do an</p> <p>5 exhaustive search of documents. My focus here was to</p> <p>6 look at the specific examples of CGMP deficiencies that</p> <p>7 apply to the class.</p> <p>8 Q. Is it fair to say, sir, that if the root cause</p> <p>9 assessment that Mylan conducted in 2018 is not listed on</p> <p>10 Exhibit A to your report, then you didn't review it in</p> <p>11 preparing your report, correct?</p> <p>12 A. Well --</p> <p>13 MR. DAVIS: Object to form.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: So the documents that I</p> <p>16 reviewed, again as I said, I didn't necessarily review</p> <p>17 all documents. I only reviewed examples that I -- as I</p> <p>18 said in my report, they were examples. It was not an</p> <p>19 exhaustive report. It was not intended to be an</p> <p>20 exhaustive report. If there were further work beyond</p> <p>21 this on merits report, probably would get into that type</p> <p>22 of thing.</p> <p>23 Q. Sure. I understand that's your testimony. But</p> <p>24 I also heard you testify yesterday that if it's not in</p> <p>25 Exhibit A, I probably haven't reviewed it. Do you</p>
<p style="text-align: right;">Page 47</p> <p>1 the answer is I don't know because I may not have looked</p> <p>2 at that because this was not an exhaustive report. It</p> <p>3 was only to identify examples.</p> <p>4 Q. (BY MR. STOY) Right. You weren't looking at</p> <p>5 the different manufacturer's process chemistry; you were</p> <p>6 just looking at GMP issues, correct?</p> <p>7 A. Well, process changes do impact CGMP. I was --</p> <p>8 but I was looking at the CGMP aspects.</p> <p>9 Q. Are you aware of how the nitrosamine impurity</p> <p>10 that was detected in Mylan's valsartan API was formed?</p> <p>11 A. I may be, but that's not an area that I looked</p> <p>12 at relative to my report.</p> <p>13 Q. Did you ever review Mylan's root cause analysis</p> <p>14 related to the nitrosamine impurity?</p> <p>15 A. Well, I did review, as I indicate in my report,</p> <p>16 the risk assessment that was conducted by Mylan.</p> <p>17 Q. The risk assessment that you reference in your</p> <p>18 report, I believe, was a 2014 document; is that correct?</p> <p>19 A. I have to go back and make sure that's a</p> <p>20 correct date. I'm not sure. If you say it's that date,</p> <p>21 it probably is. But I'm not certain what the date was</p> <p>22 without looking at the document.</p> <p>23 Q. So if it was a -- assuming I'm correct that</p> <p>24 it's a 2014 document, that document would not be Mylan's</p> <p>25 root cause assessment with regard to the nitrosamine</p>	<p style="text-align: right;">Page 49</p> <p>1 remember testifying to that?</p> <p>2 MR. DAVIS: Object to form. Object to the</p> <p>3 mischaracterizing his testimony.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: Well, the documents that I've</p> <p>6 included in my report are the documents that I reviewed</p> <p>7 that are shown in Exhibit A.</p> <p>8 Q. (BY MR. STOY) Right. And I don't see the 2018</p> <p>9 root cause analysis that Mylan conducted in Exhibit A.</p> <p>10 So if it's not in there, that means you probably didn't</p> <p>11 review it, right?</p> <p>12 A. If it's not in there, I did not review it for</p> <p>13 the purposes of this report.</p> <p>14 Q. Have you ever reviewed the results of Mylan's</p> <p>15 internal testing for nitrosamine impurities in valsartan</p> <p>16 API?</p> <p>17 A. I -- I may have. But that was not the purpose</p> <p>18 of this report. The purpose of this report was to</p> <p>19 identify examples of CGMP deficiencies.</p> <p>20 Q. (BY MR. STOY) Have you ever reviewed FDA's</p> <p>21 published testing results for nitrosamine impurities in</p> <p>22 Mylan's valsartan's finished dose?</p> <p>23 A. I may have seen those documents, but that was</p> <p>24 not particularly relevant to this particular report</p> <p>25 relative to CGMP deficiencies.</p>

<p style="text-align: right;">Page 50</p> <p>1 Q. Okay. So you may have seen those, you may not</p> <p>2 have, but you didn't consider those documents in</p> <p>3 preparing this report, correct?</p> <p>4 A. That is correct.</p> <p>5 Q. Have you ever reviewed Mylan's valsartan recall</p> <p>6 notices?</p> <p>7 A. I may have seen those, but that was not</p> <p>8 pertinent to this report.</p> <p>9 Q. Okay. So again, you wouldn't have considered</p> <p>10 those in preparing this report, right?</p> <p>11 A. That's correct because I was focusing on</p> <p>12 examples of CGMP deficiencies that applied to the class.</p> <p>13 Q. Generally speaking, do you understand that</p> <p>14 Mylan recalled valsartan containing medications in</p> <p>15 November and December of 2018?</p> <p>16 A. I don't specifically remember that. But I know</p> <p>17 there are number of recalls by number of manufacturers</p> <p>18 in that timeframe.</p> <p>19 Q. Are you aware, sir, that none of Mylan's</p> <p>20 valsartan API contained NDMA above the FDA's allowable</p> <p>21 intake limits?</p> <p>22 MR. DAVIS: Object to form.</p> <p>23 THE WITNESS: That's not something I</p> <p>24 reviewed. What I reviewed were the CGMP deficiencies.</p> <p>25 And I think as I said yesterday, the CGMP deficiencies</p>	<p style="text-align: right;">Page 52</p> <p>1 THE WITNESS: So again, I may have seen</p> <p>2 those, but that wasn't a subject of my report. So I did</p> <p>3 not review those documents relative to my report.</p> <p>4 Again, I want to state again that my report</p> <p>5 only list examples. It was not an exhaustive search of</p> <p>6 everything. It was examples related to the CGMP</p> <p>7 deficiencies related to class.</p> <p>8 Q. Do you have an understanding as to whether all</p> <p>9 of Mylan's valsartan API contained levels of NDEA that</p> <p>10 was above FDA's allowable intake limits or is that not</p> <p>11 something you consider?</p> <p>12 A. Well, I didn't -- that -- that wasn't relative</p> <p>13 to my report. The -- the one document I would probably</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 2012, 2013. So I'm aware of that. I'm not quite sure</p> <p>20 how that relates to anything because that's not</p> <p>21 necessarily relevant here.</p> <p>22 Q. Sure. And that document you just mentioned,</p> <p>23 that's a ZHP document, right?</p> <p>24 A. That was a ZHP document, right.</p> <p>25 Q. So that wouldn't have anything to do with</p>
<p style="text-align: right;">Page 51</p> <p>1 would apply to all the products and wouldn't necessarily</p> <p>2 matter whether they contained the contaminants or not.</p> <p>3 The fact that the CGMP deficiencies would indicate that</p> <p>4 all products were adulterated as I said yesterday. But,</p> <p>5 no, that wasn't relevant to this particular report.</p> <p>6 Q. (BY MR. STOY) Were you aware that the FDA had</p> <p>7 set allowable intake limits for NDMA and NDEA?</p> <p>8 A. There -- there are a number of documents that</p> <p>9 the FDA has published relative to the allowable limits,</p> <p>10 et cetera. But again, that was not relative to my</p> <p>11 particular report.</p> <p>12 Q. Sure. I'm not asking whether it was relevant</p> <p>13 to your report. I'm asking whether you were aware of</p> <p>14 it; yes or no?</p> <p>15 A. I'm aware there were very certain limits set at</p> <p>16 various times, but again, those are not documents that I</p> <p>17 reviewed as part of my report.</p> <p>18 Q. So you wouldn't know one way or the other</p> <p>19 whether Mylan issued a recall for any medications</p> <p>20 related to NDMA, correct?</p> <p>21 MR. DAVIS: Object to form. Did you say</p> <p>22 NDMA or NDEA, Frank?</p> <p>23 MR. STOY: NDMA.</p> <p>24 MR. DAVIS: Okay. Thank you. Object to</p> <p>25 form.</p>	<p style="text-align: right;">Page 53</p> <p>1 Mylan, right?</p> <p>2 A. Again, I didn't try to make the inference in my</p> <p>3 report that it did.</p> <p>4 Q. I'm sorry. I didn't -- I didn't hear your</p> <p>5 answer.</p> <p>6 A. I said I did not try to make that inference in</p> <p>7 my report.</p> <p>8 Q. Right. Because ZHP and Mylan are different API</p> <p>9 manufacturers, correct?</p> <p>10 A. Right.</p> <p>11 Q. They have different supply chains, right?</p> <p>12 A. That's correct.</p> <p>13 Q. Would it affect your opinions one way or the</p> <p>14 other if you learned that some of the batches of Mylan's</p> <p>15 valsartan API contained NDEA levels below FDA's</p> <p>16 allowable intake limits?</p> <p>17 MR. DAVIS: Object to form. Object to the</p> <p>18 extent it assumes facts not in evidence.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: No, I would not because that</p> <p>21 was not the purpose of my report. The purpose of my</p> <p>22 report was to identify the GMP deficiencies that I</p> <p>23 observed.</p> <p>24 Q. (BY MR. STOY) And because you're not -- you</p> <p>25 can't recall ever reviewing Mylan's NDEA testing, you're</p>

<p style="text-align: right;">Page 54</p> <p>1 not aware one way or the other if there was a 20-fold 2 difference between the lowest detected level of NDEA and 3 the highest detected level of NDEA; is that right? 4 MR. DAVIS: Object to form. 5 THE WITNESS: Again, that's not -- not a 6 situation that I reviewed because it was not relevant to 7 identifying the CGMP deficiencies. 8 Q. (BY MR. STOY) So you don't think it's relevant 9 whether there was variance from one batch to the next 10 regarding the content of NDEA in Mylan's API. Is that 11 your testimony? 12 MR. DAVIS: Object to form. Object to the 13 extent it mischaracterizes his testimony. 14 THE WITNESS: That's -- that's not what I 15 said. If there were varying levels, it would certainly 16 indicate that there was something out of control which 17 you would want a consistent process. But that's not 18 something I reviewed relative to this report. 19 Q. (BY MR. STOY) Why is it that you don't think 20 that it's relevant whether the levels were different 21 from one batch to the next for the purposes of your 22 report? 23 A. Because I was identifying CGMP deficiencies. 24 And as I said before, relative to the CGMP deficiencies, 25 it's not relevant whether there was any contaminant at</p>	<p style="text-align: right;">Page 56</p> <p>1 A. That's not what I said. What I said was I was 2 provided with a complete transcripts and I skimmed 3 through the transcripts. I did not necessarily read 4 every sentence in the very extensive depositions 5 provided. I skimmed through and I asked for what -- 6 where there might be specific references for the things 7 I was looking for. But if you -- I want to make sure 8 you understand that I didn't necessarily review every 9 sentence in the deposition. I wanted to review the 10 pertinent points relative to my report. 11 Q. How did you -- and I'm just asking with respect 12 to the Mylan deposition transcripts, how did you 13 determine which portions of those transcripts would 14 contain pertinent information? 15 A. So it's the same as I said before is I asked 16 counsel what sections might relate to the particular 17 aspects that I'm trying to review here, and they 18 directed me to those sections. 19 Q. And those were the sections or some of the 20 sections that ultimately appear in your report? 21 A. That's correct. 22 Q. In the text, correct? 23 A. That's correct. 24 Q. And with respect to -- so putting deposition 25 transcripts to one side, with respect to the documents</p>
<p style="text-align: right;">Page 55</p> <p>1 all if they were not made in a compliant manner. 2 Q. I want to talk a little bit about what you did 3 to form the basis for your opinions regarding Mylan. 4 Based on your report, it looks to me like 5 you went through certain documents and deposition 6 testimony that was provided to you by plaintiff's 7 counsel; is that correct? 8 MR. DAVIS: Object to form. Object to the 9 characterization. 10 You can answer. 11 THE WITNESS: Yes, these documents were 12 provided by plaintiff's counsel. As I said yesterday, 13 initially, when I started this process at the very 14 beginning, I had a list of documents that I thought 15 would be useful to review as part of this overall 16 process. This goes back some time ago. So it may have 17 been the documents I had requested. It may have been 18 other documents. So I'm not sure which -- which would 19 fall into which category. But the documents I reviewed 20 for the report are the ones that are listed in 21 Exhibit A. 22 Q. (BY MR. STOY) Right. And you -- I think you 23 testified earlier that with respect to the deposition 24 testimony you didn't review those documents in their 25 entirety; is that correct?</p>	<p style="text-align: right;">Page 57</p> <p>1 that you referenced, how did you go about selecting 2 those documents for inclusion in your report? 3 A. So as I've indicated, I tried to pull up 4 examples that would relate to -- CGMP deficiencies that 5 related to the class, and again, I didn't necessarily 6 review other -- I may have reviewed other documents that 7 would also be relevant, but I only included examples in 8 my report. 9 Q. Did you read the full documents that are 10 included in your report? 11 A. Well, some of these documents are hundreds of 12 pages. So I reviewed the -- I reviewed the sections 13 that were relevant to the sections I referenced. 14 Q. And how did you -- same question as with the 15 deposition testimony, how did you go about determining 16 which sections were relevant? 17 A. Well, for example, let's go to my -- my 18 Paragraph 130. In that regard I reviewed the entire 19 document. This had to do with the risk assessment that 20 was eventually ultimately classified as low risk. I did 21 review that entire document because the entire document 22 was relevant to my report. 23 Q. Look specifically at Paragraph 131 in your 24 report. 25 A. Which paragraph?</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. Well, actually, first of all, I want to ask you 2 about Paragraphs 129 through 133 in your report -- 3 A. Okay. 4 Q. Let me know when you're there. 5 A. I'm there. 6 Q. Okay. You made some statements here about 7 Mylan's internal operations, correct? 8 A. When you say, "internal operations," I make 9 reference to the risk assessment in 2014. 10 Q. Right. That would be an internal Mylan 11 document, correct? 12 A. That's correct. 13 Q. These observations that you make in 129 14 through 133 would not be pertinent to any other 15 defendant besides Mylan, correct? 16 A. That's probably the case because these were 17 Mylan risk assessments. 18 Q. Sure. 19 MR. DAVIS: Let me -- I'm going to place an 20 objection on that last question. 21 THE WITNESS: So I guess maybe to clarify 22 that it would be relevant to Mylan and the class related 23 to Mylan products. 24 Q. (BY MR. STOY) What do you mean by that? 25 A. Well, it -- it would relate to all the products</p>	<p style="text-align: right;">Page 60</p> <p>1 peaks, correct? 2 A. My comment -- I'm sorry. 3 MR. DAVIS: Object to form. Go ahead. 4 THE WITNESS: So my comment is they should 5 have investigated these peaks and -- which is what the 6 FDA also got into as well. And so not properly 7 investigating these unknown peaks was the -- was the 8 issue. But I'm not offering an opinion on the specific 9 chromatograms. 10 Q. (BY MR. STOY) Right. You're just restating 11 what you think FDA said with regard to this -- 12 A. No. 13 Q. -- because you didn't analyze them yourself, 14 right? 15 MR. DAVIS: Object to form. Objection to 16 the mischaracterization of his testimony. 17 THE WITNESS: No. What you said is not 18 correct. I also reviewed the depositions from the Mylan 19 employees relative to the situation. 20 Q. (BY MR. STOY) In Paragraph 132, which you just 21 referenced, you state that FDA made some observations 22 about unknown peaks in some document; is that right? 23 A. I do. 24 Q. Do you know if the unknown peaks that you 25 reference --</p>
<p style="text-align: right;">Page 59</p> <p>1 and pills that were distributed by Mylan relative to the 2 specific issue. 3 Q. Look specifically at Paragraph 131 on Page 26 4 there. Take a second and read it for me. Not out loud. 5 Just to yourself. 6 A. Okay. I've read it. 7 Q. Okay. You make reference to some 8 chromatography testing of the solvent ortho-xylene; is 9 that correct? 10 A. I do. 11 Q. Did you personally review any of that 12 chromatography testing? 13 A. I did not review the specific chromatograms. I 14 did not review those. It wasn't relevant to my report 15 to review the specific chromatograms. 16 Q. So you did not undertake any analysis of 17 yourself of these so-called unknown peaks; is that 18 correct? 19 A. No, I relied on -- on the Mylan testimony to 20 indicate that they never investigated these unknown 21 peaks. That -- that was what I looked at. Mylan 22 themselves indicated they had not done a -- investigated 23 the unknown peaks. 24 Q. So you're not offering any opinion of whether 25 Mylan should or should not have investigated these</p>	<p style="text-align: right;">Page 61</p> <p>1 THE REPORTER: Wait. I can't hear you. 2 THE WITNESS: I can't either. 3 MR. DAVIS: Sorry, Frank. We didn't get 4 that. Can you repeat the question? 5 MR. STOY: Sure. Can -- can you hear me 6 now? 7 MR. DAVIS: Yes. 8 Q. (BY MR. STOY) Do -- do you know if the unknown 9 peaks that you reference in Paragraph 132 are the same 10 ones referenced in Paragraph 131? 11 A. I'm not certain, but it's not particularly 12 relevant. The real key is that Mylan should have been 13 investigating these unknown peaks. So whether the same 14 or not is not relevant. The fact is that they weren't 15 properly investigated. That's the point I was making. 16 Q. Well, if they're not the same, how do you know 17 that they weren't properly investigated? 18 MR. DAVIS: Objection to form. Objection 19 to the mischaracterization of the testimony. 20 You can answer. 21 THE WITNESS: Mylan themselves in their 22 depositions basically stated that. 23 Q. (BY MR. STOY) How do you know that the 24 deposition testimony is referring to the same peaks? 25 A. I don't. But it's not relevant. It doesn't</p>

<p style="text-align: right;">Page 62</p> <p>1 matter.</p> <p>2 Q. So your testimony is that any failure to</p> <p>3 investigate any unknown peak anywhere in the company</p> <p>4 somehow relates to valsartan?</p> <p>5 MR. DAVIS: Objection.</p> <p>6 Q. (BY MR. STOY) I'm not following your</p> <p>7 testimony, sir.</p> <p>8 MR. DAVIS: Object to form. Objection to</p> <p>9 the mischaracterization of his testimony.</p> <p>10 THE WITNESS: So what I said and I'll say</p> <p>11 again is if in a chromatogram you have unknown peaks,</p> <p>12 it's the responsibility of the company to investigate</p> <p>13 and determine what those unknown peaks represent.</p> <p>14 Q. (BY MR. STOY) And you don't know whether they</p> <p>15 were investigated or not beyond what you read in</p> <p>16 documents, right?</p> <p>17 A. Well, I'm referring back to what Mylan</p> <p>18 themselves said.</p> <p>19 Q. Take a look on the next page. You cite to an</p> <p>20 FDA inspection document there, right? I think it's --</p> <p>21 it's in Footnote 68, 69, and 70, it's the same document;</p> <p>22 is that right?</p> <p>23 A. That's right.</p> <p>24 Q. You quote some excerpts from that document,</p> <p>25 correct?</p>	<p style="text-align: right;">Page 64</p> <p>1 Q. Did you do anything else to render these</p> <p>2 opinions that appear on this page as they pertain to</p> <p>3 Mylan besides review this report?</p> <p>4 MR. DAVIS: Object to form.</p> <p>5 THE WITNESS: Well, I reviewed the</p> <p>6 documents I've listed in my Exhibit A, which may include</p> <p>7 other things. And again, as I said before, these were</p> <p>8 just examples.</p> <p>9 Q. (BY MR. STOY) Are you aware of which Mylan</p> <p>10 facilities manufacture valsartan API?</p> <p>11 A. I may be. I just don't recall at hand.</p> <p>12 Q. Would you agree with me that FDA observations</p> <p>13 at a facility that did not manufacture valsartan API</p> <p>14 would not be relevant to your report?</p> <p>15 MR. DAVIS: Object to form.</p> <p>16 THE WITNESS: So my report addressed the --</p> <p>17 addressed the points relative to CGMP deficiencies.</p> <p>18 That's what was relevant, the CGMP deficiencies that</p> <p>19 were observed.</p> <p>20 MR. DAVIS: Would you read my question</p> <p>21 back, please, Madam Reporter?</p> <p>22 (Requested question was read.)</p> <p>23 THE WITNESS: They would be --</p> <p>24 Q. (BY MR. STOY) I would like you to answer that</p> <p>25 question.</p>
<p style="text-align: right;">Page 63</p> <p>1 A. I do.</p> <p>2 Q. Take a look at Paragraph 136 on Page 27. Let</p> <p>3 me know when you've had a chance to read it.</p> <p>4 A. Okay.</p> <p>5 Q. You're quoting the February 28, 2020 Unit 7 FDA</p> <p>6 establishment inspection report in that paragraph,</p> <p>7 correct?</p> <p>8 A. I am.</p> <p>9 Q. Tell me what analysis you performed related to</p> <p>10 this document.</p> <p>11 MR. DAVIS: Object to the form. Vague.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: I'm referencing what the FDA</p> <p>14 found during the inspection of which they included in</p> <p>15 their established inspection report.</p> <p>16 Q. (BY MR. STOY) Right. You're just quoting what</p> <p>17 FDA says, right?</p> <p>18 A. I am quoting what FDA says, because I was not</p> <p>19 in the facility, but the FDA was and they -- they issued</p> <p>20 their report.</p> <p>21 Q. So you weren't able to do any independent</p> <p>22 analysis to verify what FDA said, correct? You're just</p> <p>23 repeating what they put in the report?</p> <p>24 A. And I have no reason to believe that the FDA</p> <p>25 was incorrect.</p>	<p style="text-align: right;">Page 65</p> <p>1 A. They would be relevant because of the</p> <p>2 indicative of a corporate noncompliance. So if it</p> <p>3 occurs to one facility, it would probably occur at</p> <p>4 another facility from a CGMP standpoint, and Mylan</p> <p>5 should be responsible ensuring that all facilities are</p> <p>6 CGMP compliant.</p> <p>7 Q. So it's your testimony that CGMP issues that</p> <p>8 occur at one facility in a company -- in a global</p> <p>9 company are also likely to occur at another facility in</p> <p>10 a global company?</p> <p>11 MR. DAVIS: Object to form. Objection to</p> <p>12 the mischaracterization of his testimony.</p> <p>13 THE WITNESS: That's not what I said. What</p> <p>14 I said was if a CGMP deficiency occurs -- occurs in one</p> <p>15 operation, most pharmaceutical companies would go and</p> <p>16 investigate the other facilities to ensure they don't</p> <p>17 have similar situation in those to facilities because</p> <p>18 they could well have those situations.</p> <p>19 Q. (BY MR. STOY) So my hand has facilities in,</p> <p>20 let's say, Puerto Rico. If the FDA goes into Puerto</p> <p>21 Rico and makes observations about GMPs, it's your --</p> <p>22 it's your position that Mylan then should initiate</p> <p>23 investigations at all of its other facilities all over</p> <p>24 the world?</p> <p>25 MR. DAVIS: Object to form. Objection,</p>

<p style="text-align: right;">Page 66</p> <p>1 incomplete hypothetical.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: So if deficiencies are found</p> <p>4 as for your example in a Puerto Rican facility, I think</p> <p>5 Mylan should, in fact, go and investigate the similar</p> <p>6 CGMP deficiencies occurring at other facilities. And I</p> <p>7 believe that's the expectation of the agency, and I</p> <p>8 would expect that to occur. And just going back to my</p> <p>9 prior life at Baxter, that's what we did.</p> <p>10 Q. (BY MR. STOY) So if you had FDA make</p> <p>11 observations that were specific to one facility when you</p> <p>12 were at Baxter, your testimony is that Baxter would</p> <p>13 initiate investigations at all of its other</p> <p>14 manufacturing facilities?</p> <p>15 A. What I said -- what I said was if we had a</p> <p>16 situation in one facility, we would -- had GMP</p> <p>17 deficiencies, we would ensure that we examine the other</p> <p>18 appropriate facilities to ensure we didn't have similar</p> <p>19 deficiencies and/or put corrective actions in place not</p> <p>20 have those situations.</p> <p>21 Q. The report that -- let's go back to the Unit 7</p> <p>22 EIR, which it comes from a 2020 inspection. You'd agree</p> <p>23 with me that -- that the 2020 inspection occurred years</p> <p>24 after the valsartan recall, correct?</p> <p>25 A. It did occur after the recalls, yes.</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. (BY MR. STOY) You don't know one way or the</p> <p>2 other whether Unit 7 ever manufactured valsartan, right?</p> <p>3 A. Again, no. And my -- but my point is -- and we</p> <p>4 went through extensively yesterday in this deposition --</p> <p>5 it doesn't matter if there is CGMP's deficiencies in a</p> <p>6 facility. All of the -- all of the drug products</p> <p>7 produced in that facility could be considered to be</p> <p>8 adulterated. So if there's an issue in one part of the</p> <p>9 facility, it would apply to other parts of the facility.</p> <p>10 Q. Sure. But if that facility didn't make</p> <p>11 valsartan, then it wouldn't apply to valsartan, right?</p> <p>12 MR. DAVIS: Objection.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: So again, my -- my -- my</p> <p>15 comments related to CGMP deficiencies not necessarily</p> <p>16 related to valsartan related to CGMP deficiencies, but</p> <p>17 it does apply to the class. And the point was if there</p> <p>18 was a deficiency -- hold on a second.</p> <p>19 MR. DAVIS: Sorry. The witness lost his</p> <p>20 microphone.</p> <p>21 THE WITNESS: If there was a deficiency in</p> <p>22 one part of the facility, there might be deficiencies in</p> <p>23 another part of the facility.</p> <p>24 Q. (BY MR. STOY) Okay. But that still doesn't</p> <p>25 explain to me how that would apply to valsartan which if</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. And are you aware of the fact that at the time</p> <p>2 of that inspection, Mylan's valsartan was back on the</p> <p>3 market?</p> <p>4 MR. DAVIS: Object to form and objection to</p> <p>5 the mischaracterization of the facts.</p> <p>6 THE WITNESS: So to answer your question, I</p> <p>7 may be aware of it. That's not relevant to my report.</p> <p>8 Q. (BY MR. STOY) Why is it not relevant to your</p> <p>9 report?</p> <p>10 A. Because in my report I used examples for CGMP</p> <p>11 deficiencies that existed within Mylan, and whether they</p> <p>12 were back on the marketplace at some point in the future</p> <p>13 is not relevant to my report as to what happened at the</p> <p>14 time I indicated there were CGMP deficiencies. All that</p> <p>15 says is they eventually corrected them.</p> <p>16 Q. Okay. But you're citing from a 2020 report and</p> <p>17 a 2020 inspection that occurred after FDA had allowed</p> <p>18 Mylan to return valsartan to the market, right?</p> <p>19 MR. DAVIS: Object to form. Again,</p> <p>20 objection to the mischaracterization of the facts.</p> <p>21 THE WITNESS: I don't know the timing on</p> <p>22 when valsartan came back to the -- Mylan's product came</p> <p>23 back to market. Again, it's not relevant. The fact</p> <p>24 that it came back is totally irrelevant to my report</p> <p>25 relative to the CGMP deficiencies.</p>	<p style="text-align: right;">Page 69</p> <p>1 it was not manufactured at that facility.</p> <p>2 MR. DAVIS: Object to form.</p> <p>3 THE WITNESS: So I'm saying the same thing</p> <p>4 again is that if there's a CGMP deficiency in one</p> <p>5 operation in one part of the facility or another</p> <p>6 facility, it should be the responsibility of the</p> <p>7 pharmaceutical manufacturer to ensure that those</p> <p>8 deficiencies are corrected across the operations, all</p> <p>9 the operations.</p> <p>10 But that's not -- that's not really the</p> <p>11 subject of my report. I didn't get into that kind of</p> <p>12 detail. My point is my report identified examples of</p> <p>13 CGMP deficiencies. There may be others and if I had</p> <p>14 additional information at some point, we would review</p> <p>15 that information in light of this. This is not a merits</p> <p>16 report. It's -- it's an attempt to identify examples of</p> <p>17 CGMP deficiencies.</p> <p>18 Q. (BY MR. STOY) Sure. But just to be clear, the</p> <p>19 document that you are relying on on this page of your</p> <p>20 report in order to form your opinions is this Unit 7 EIR</p> <p>21 document, right?</p> <p>22 MR. DAVIS: Object to form.</p> <p>23 Q. (BY MR. STOY) That's the one you're quoting,</p> <p>24 right?</p> <p>25 A. That's -- that is the one I'm referencing. If</p>

<p style="text-align: right;">Page 70</p> <p>1 you're referring to Section 136, that's the one I'm 2 referencing, yes.</p> <p>3 Q. And you don't believe that the timing of when 4 FDA issued any warning letter to Mylan related to a 5 facility that manufactured valsartan, you don't believe 6 the timing of that is relevant to your report. Is that 7 your testimony?</p> <p>8 MR. DAVIS: Objection to form and object, 9 vague and ambiguous.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: The timing was not the aspect 12 of my report. The issue was identified what I 13 considered to be seriously GMP deficiencies that existed 14 and I reference those. But the timing relative to any 15 document that the FDA would have put out was not 16 particularly relevant to my examples that I reference in 17 my report.</p> <p>18 Q. (BY MR. STOY) Could Mylan have returned to the 19 market with valsartan without FDA's approval to do so?</p> <p>20 MR. DAVIS: Object to vague and ambiguous 21 as to Mylan's return to the market of valsartan.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: I don't know. They may or 24 may not have been able to. I don't know because that 25 wasn't a topic that I reviewed as part of my report.</p>	<p style="text-align: right;">Page 72</p> <p>1 whether Mylan ever went back on the market with 2 valsartan?</p> <p>3 A. So I -- I may have seen that they went back to 4 the market. I don't know. But again, I'll say again it 5 wasn't relevant to the CGMP deficiencies that I was 6 reviewing and putting to my report.</p> <p>7 Q. The FDA never placed Mylan on import letter, 8 correct?</p> <p>9 A. I don't believe so, but I'm not certain. And 10 again, that's not relevant to my report.</p> <p>11 Q. Are you aware that the facilities that 12 manufactured valsartan API continued to supply drug 13 products with FDA approval throughout the entire time 14 period that we've been discussing?</p> <p>15 A. I'm not particularly aware of that. But again, 16 it's not relevant. All I'm going to say again what I 17 identified were examples of CGMP deficiencies. The 18 statement that you make is not relevant to my report and 19 it's not relevant to what I reviewed.</p> <p>20 Q. Do you think the FDA would allow a drug 21 manufacturer to sell adulterated and misbranded products 22 in the United States?</p> <p>23 MR. DAVIS: Object to form.</p> <p>24 THE WITNESS: Well, it would depend upon 25 that particular situation and what the FDA determined.</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. (BY MR. STOY) Well, I'm not -- I'm asking you 2 a more general question based on your, you know, 40-plus 3 years of experience in this industry.</p> <p>4 When a -- when a company takes a product 5 off the market, can that company put the product back on 6 the market without FDA's approval?</p> <p>7 MR. DAVIS: Object to form. Objection, 8 improper hypothetical. It's contrary to the facts of 9 the case.</p> <p>10 THE WITNESS: So every example would be 11 different. So I -- you're giving me a hypothetical 12 situation. In some cases the FDA might want to approve 13 the product going back to the market. Other cases they 14 may not have to. It really depends. And again, it's 15 not relevant to what I was looking at and that was not a 16 topic, a focus I was looking at relative to my report 17 relative to the CGMP deficiencies.</p> <p>18 Q. (BY MR. STOY) So you don't -- you don't know 19 whether Mylan ever went back on the market with 20 valsartan or not; is that your testimony?</p> <p>21 MR. DAVIS: Object to -- sorry, Frank, I 22 didn't mean to cut you off there. Do you want to repeat 23 that?</p> <p>24 Q. (BY MR. STOY) Sorry.</p> <p>25 You do not know one way or the other</p>	<p style="text-align: right;">Page 73</p> <p>1 I'm not going to speak for the FDA, what the FDA may or 2 -- might or might not do.</p> <p>3 Q. (BY MR. STOY) So you don't have an opinion on 4 that one way or the other?</p> <p>5 A. I don't because it's not relevant, and I'm not 6 going to speak for the FDA. FDA does different things 7 relative to different circumstances. And I'm not going 8 to speak for the FDA.</p> <p>9 Q. You testified yesterday that when you were at 10 Baxter, the FDA issued a warning letter to the company 11 in, I think, 2000; is that right?</p> <p>12 A. I did -- so I can't -- you're a little --</p> <p>13 Q. Oh, I'm sorry. I'm sorry. I apologize.</p> <p>14 You -- you testified yesterday that when 15 you were with Baxter, the FDA issued a warning letter to 16 one of Baxter's facilities; is that right?</p> <p>17 A. I was provided with a warning letter yesterday 18 that showed -- it showed that Baxter did receive a 19 warning letter, yes. I --</p> <p>20 Q. Right. I think you were copied on that 21 document, right?</p> <p>22 A. I was.</p> <p>23 Q. And I believe you testified, and if I misstate 24 this, correct me, but I believe you testified that based 25 on that warning letter, you considered all the products</p>

<p style="text-align: right;">Page 74</p> <p>1 manufactured at that facility to be adulterated as a 2 result of the warning letter. Is that your testimony? 3 A. So that -- I believe that's what I said 4 yesterday. But that's not particularly relevant to this 5 report. 6 Q. Okay. Well, I just want to unpack that a 7 little bit. 8 Do you believe that the warning letter 9 rendered all of Baxter's products adulterated 10 retrospectively? 11 MR. DAVIS: Object to form and vague and 12 ambiguous as to retrospectively. 13 You can answer. 14 THE WITNESS: You're asking me to give an 15 opinion on something that happened 22 years ago. I 16 don't recall. 17 Q. (BY MR. STOY) Okay. Well, you already gave 18 the opinion and you've restated it this morning that you 19 believe that that warning letter rendered all of 20 Baxter's products adulterated. 21 A. No, I did not say that. 22 Q. What did you say? 23 A. We're talking about that specific facility. 24 Q. Right. I'm sorry. At that specific facility, 25 right?</p>	<p style="text-align: right;">Page 76</p> <p>1 situation was back then. 2 Q. (BY MR. STOY) Do you know if Baxter took any 3 products off the market as a result of that warning 4 letter? 5 A. I don't recall what Baxter did back in those 6 days. I don't know. I'm sure -- I'm sure if we wanted 7 to research that, we could determine whether, in fact, 8 that happened. But 22 years ago, I don't recall. 9 Q. Can you explain to me how it would be that the 10 FDA could permit adulterated products to be sold in the 11 United States under the FDCA? 12 A. No. I -- I'm not -- I'm not going to answer 13 that because I don't know because you're asking me to 14 speak for the FDA again, and I can't speak for the FDA. 15 Every circumstance would be different, and I'm not going 16 to speak for the FDA. 17 Q. But you've quoted the FDA extensively in your 18 report, right? 19 A. I quoted the FDA versus the investigator's 20 statements and the EIRs that I referenced. 21 Q. And you can't speak to the truth of those 22 statements one way or the other, right? 23 MR. DAVIS: Object to form. 24 THE WITNESS: I have no reason to believe 25 that any statements that were made in the EIRs are</p>
<p style="text-align: right;">Page 75</p> <p>1 A. Right. I believe that's what the warning 2 letter probably said so... 3 Q. Would that warning letter have rendered 4 products at other Baxter facilities adulterated? 5 A. I don't recall the exact circumstances of that 6 letter. I don't know and I don't want to speak to 7 something that happened 22 years ago. 8 MR. DAVIS: Frank, let me just place a 9 continuing objection on this. This was covered at 10 length yesterday. I don't think it's appropriate to -- 11 for multiple attorneys to recover the same ground over 12 and over again. 13 MR. STOY: Well, I'm asking different 14 questions, John. But your -- your objection is noted. 15 Q. (BY MR. STOY) I want to understand, though, 16 do -- do you believe that the warning letter -- you're 17 not sure about retrospectively. What about -- did that 18 warning letter to Baxter render products manufactured at 19 that facility prospectively adulterated? 20 MR. DAVIS: Object to form. Again, vague 21 and ambiguous as to what you mean by "prospectively." 22 You can answer it if you understand it. 23 THE WITNESS: I don't recall. We're going 24 back some 22 years ago. We'd have to go back -- I don't 25 even have those files so I don't recall exactly what the</p>	<p style="text-align: right;">Page 77</p> <p>1 incorrect or misstated. 2 Q. (BY MR. STOY) Right. You wouldn't have any 3 reason to believe one way or the other, right? 4 A. Well, typically, in my experience the FDA when 5 they put in quotes in the EIRs, they are very specific. 6 And in all my years of experience, I've never seen those 7 to be incorrect statements. 8 Q. So when you were at Baxter, you never disagreed 9 with anything that the FDA put in a report? 10 A. That's not what I said. 11 Q. But that's my question. 12 A. Okay. So yes, we did disagree with the FDA on 13 many occasions. So I want to clarify. 14 Q. I'm sorry. What's your answer? 15 A. So to clarify, sometimes we would get reports 16 from the FDA that we did not agree with. We had 17 discussions, and the FDA would respond. Sometimes the 18 FDA agreed with us. Sometimes they didn't agree. 19 MR. STOY: Okay. I don't have any further 20 questions for you, Mr. Quick. Thank you. 21 THE WITNESS: Thank you. 22 MR. DAVIS: Anybody else? 23 UNIDENTIFIED SPEAKER: Is attorney's 24 counsel asking any questions. 25 UNIDENTIFIED SPEAKER: Let's give this a</p>

<p style="text-align: right;">Page 78</p> <p>1 second because I do believe there are other counsel. 2 Why don't we go off the record for a minute. 3 VIDEOGRAPHER: Off the record 10:00 a.m. 4 (Discussion off the record.) 5 VIDEOGRAPHER: We are back on the record -- 6 we are back on the record at 10:18 a.m. 7 MR. DAVIS: Before you start, Steve, I just 8 want to place on the record that a break was commenced 9 at 10 o'clock a.m. and at the defendant's request and 10 we're now back on the record almost 20 minutes later. 11 Thanks. You can start. 12 EXAMINATION 13 Q. (BY MR. HUNCHUCK) Mr. Quick, my name Steven 14 Hunchuck, and I'm going to ask you some questions 15 regarding the Aurobindo defendants and your opinions 16 about them. 17 If you could please pull up your report and 18 turn to Paragraph 173. 19 A. Okay. 20 Q. Okay. At 173 it says, (Reading:) Aurobindo 21 lacked competent quality management system in place to 22 adequately investigate the root cause of the nitrosamine 23 impurities. 24 THE REPORTER: Can you speak up or get 25 closer to the mic?</p>	<p style="text-align: right;">Page 80</p> <p>1 MR. HUNCHUCK: I'm getting a delay on your 2 end as well. 3 MR. GOLDBERG: I believe that the reporter 4 had logged out during the break and logged back in. And 5 I don't know if that had affected the audio or 6 something. Maybe it would be a good idea to try and 7 have her leave again and rejoin and maybe that will fix 8 whatever issue we're having. 9 MR. HUNCHUCK: If you want to go off the 10 record to fix this, we can do that. 11 VIDEOGRAPHER: Off the record 10:21 a.m. 12 (Off the record.) 13 VIDEOGRAPHER: We are back on the record 14 10:26 a.m. 15 Q. (BY MR. HUNCHUCK) Mr. Quick, going back to 16 Paragraph 173, what -- what steps did Aurobindo take to 17 investigate the route cause of the nitrosamine 18 impurities? 19 A. Well, the reason -- the reason -- reason for my 20 statement there was the fact that the company received 21 the FDA warning letter. If, in fact, there was an 22 adequate quality system -- quality adequate system 23 placed, they probably wouldn't have received a warning 24 letter. And having reviewed what Lantech did, it was 25 very clear that the company did not do an adequate job</p>
<p style="text-align: right;">Page 79</p> <p>1 MR. DAVIS: Hey, Steven, we're having 2 trouble hearing you. You're either muffled. It's like 3 a combination of being muffled and low volume. 4 MR. HUNCHUCK: Sorry. 5 Q. (BY MR. HUNCHUCK) Looking at Paragraph 173 6 say, (Regarding:) Aurobindo lacked the competent 7 quality management system in place to adequately 8 investigate the root cause in nitrosamine impurities. 9 Can you please explain the basis for your 10 statement "adequately investigated"? 11 A. The reason for this is the FDA warning 12 letter that was issued -- 13 Q. I cannot hear you, Mr. Quick. 14 MR. DAVIS: Can you not hear him, Steven? 15 MR. HUNCHUCK: Try again, please. 16 MR. DAVIS: Try your answer again, if you 17 remember the question. 18 THE WITNESS: Yeah, I do. The reason for 19 that statement is the FDA warning letter that was issued 20 to the company relative to the issues in this case. 21 Q. (BY MR. HUNCHUCK) Do you know what steps 22 Aurobindo took during that investigation? 23 A. It's hard to hear you. 24 MR. GOLDBERG: Counsel, just so you know, 25 the audio sequence is very delayed. I know that the --</p>	<p style="text-align: right;">Page 81</p> <p>1 of managing Lantech. 2 Q. Well, what steps did Aurobindo take to 3 investigate the nitrosamine impurities? 4 A. I didn't review all the steps that they -- that 5 they took or didn't take. But whatever they did was 6 inadequate. 7 Q. So you're basing your opinion on the FDA 8 warning letter then, correct? 9 A. I'm also basing it on the warning letter that 10 went to Lantech after this occurred, and obviously, they 11 had the same issues with Lantech which, in fact, the 12 company should have known. 13 Q. Do you know what was missing from Aurobindo's 14 investigation? 15 MR. DAVIS: Object to form. 16 THE WITNESS: Well, we could go through all 17 the issues in the warning letter, all the issues in the 18 warning letter to Lantech. Again -- 19 Q. (BY MR. HUNCHUCK) Did you investigate its 20 products from nitrosamines which is in your report? 21 MR. DAVIS: Is there a question there, 22 Steven? 23 Q. (BY MR. STROY) Do you know what was missing 24 from Aurobindo's investigation? 25 MR. DAVIS: Object to form. Objection,</p>

<p style="text-align: right;">Page 82</p> <p>1 asked and answered.</p> <p>2 THE WITNESS: So I did not go through all</p> <p>3 the specifics in terms of the specific investigations.</p> <p>4 But clearly the fact that all of this occurred at</p> <p>5 Lantech clearly indicates that they did not have proper</p> <p>6 investigations and/or proper review of Lantech.</p> <p>7 Q. (BY MR. HUNCHUCK) Aurobindo's route synthesis</p> <p>8 was for its false API does not create nitrosamine; is</p> <p>9 that correct?</p> <p>10 A. I --</p> <p>11 MR. DAVIS: Object to form. Objection</p> <p>12 outside the scope.</p> <p>13 THE WITNESS: You're hard to hear.</p> <p>14 Q. (BY MR. HUNCHUCK) I can assure you I'm talking</p> <p>15 very loudly into my computer.</p> <p>16 Are you aware that AB's route synthesis</p> <p>17 does not create nitrosamines?</p> <p>18 MR. DAVIS: Object to form. Same</p> <p>19 objections as before.</p> <p>20 THE WITNESS: Again, that's not a topic I</p> <p>21 particularly reviewed relative to my report. My report</p> <p>22 was addressing examples of CGMP deficiencies.</p> <p>23 Q. (BY MR. HUNCHUCK) Okay. You testified</p> <p>24 yesterday that a manufacturer is supposed to</p> <p>25 characterize their impurities and know what they are; is</p>	<p style="text-align: right;">Page 84</p> <p>1 would have happened.</p> <p>2 Q. (BY MR. HUNCHUCK) Mr. Quick, I haven't gotten</p> <p>3 to overseeing Lantech. I'm still on the investigation</p> <p>4 of the nitrosamine.</p> <p>5 How was Aurobindo to identify the</p> <p>6 nitrosamine in a product that does not synthesize</p> <p>7 nitrosamine?</p> <p>8 MR. DAVIS: Object to form.</p> <p>9 THE WITNESS: Well, the issue is the fact</p> <p>10 that the improper investigations is to determine what</p> <p>11 they were, what the impurities were.</p> <p>12 Q. (BY MR. HUNCHUCK) But you don't know what</p> <p>13 steps Aurobindo took to investigate; is that correct?</p> <p>14 A. All I know is what the FDA stated in the</p> <p>15 warning letter.</p> <p>16 Q. Okay. Aurobindo did determine the root cause</p> <p>17 of its nitrosamine impurities; is that correct?</p> <p>18 A. I'm not certain. Again, I'm only -- I have --</p> <p>19 I have limited documents to look at relative to this</p> <p>20 particular situation, and I'm relying on the FDA's</p> <p>21 warning letter and also the warning letter that in</p> <p>22 circulation to Lantech.</p> <p>23 Q. Are you aware that the nitrosamines -- excuse</p> <p>24 me. Strike that.</p> <p>25 Are you aware that the amount of</p>
<p style="text-align: right;">Page 83</p> <p>1 that correct?</p> <p>2 A. That's correct.</p> <p>3 Q. Okay. If AB's route synthesis -- when I say</p> <p>4 "AB," I mean Aurobindo -- if AB's route synthesis does</p> <p>5 not create nitrosamines, how was AB supposed to</p> <p>6 determine that nitrosamines were present?</p> <p>7 A. The --</p> <p>8 MR. DAVIS: Object to form. You can</p> <p>9 answer.</p> <p>10 THE WITNESS: The issue was the fact that</p> <p>11 these were not being properly investigated. It doesn't</p> <p>12 matter what they were. If they're unidentified peaks,</p> <p>13 they should be investigated to determine what they are.</p> <p>14 Q. (BY MR. HUNCHUCK) And what steps do you --</p> <p>15 does -- what steps should Aurobindo have taken to</p> <p>16 investigate those peaks that you referred to?</p> <p>17 MR. DAVIS: Object to form and object,</p> <p>18 asked and answered already.</p> <p>19 THE WITNESS: So clearly, Lantech was out</p> <p>20 of control. And the company was using Lantech for</p> <p>21 recycled solvents, and I mean, that came up I think in</p> <p>22 the warning letter that was issued to the company and</p> <p>23 also the warning letter that was issued to Lantech. Had</p> <p>24 they done a proper supplier evaluation and monitoring</p> <p>25 the supplier of recycled solvents, none of this probably</p>	<p style="text-align: right;">Page 85</p> <p>1 nitrosamines varied among the manufacturers' products?</p> <p>2 MR. DAVIS: Object to form.</p> <p>3 THE WITNESS: There may have been some</p> <p>4 variability, but that's not at all relevant to my report</p> <p>5 relevant to the CGMP deficiencies.</p> <p>6 Q. (BY MR. HUNCHUCK) Do you have an understanding</p> <p>7 as to why there was variability in the nitrosamines?</p> <p>8 A. I --</p> <p>9 MR. DAVIS: Object to form. Objection,</p> <p>10 outside the scope.</p> <p>11 THE WITNESS: That's not an area I</p> <p>12 reviewed. It was not part of the assignment relative to</p> <p>13 this report relative to the CGMP deficiencies. We may</p> <p>14 get into that later on if we go beyond this report to a</p> <p>15 merits report. But that has not been the scope of this</p> <p>16 report.</p> <p>17 Q. (BY MR. HUNCHUCK) Do you know what</p> <p>18 manufacturer of valsartan products inspected their</p> <p>19 products for nitrosamines prior to 2018?</p> <p>20 MR. DAVIS: Object -- sorry. No objection.</p> <p>21 THE WITNESS: I missed the first part of</p> <p>22 that.</p> <p>23 MR. DAVIS: Can you repeat the question,</p> <p>24 Steven?</p> <p>25 Q. (BY MR. HUNCHUCK) Yes. Do you know which</p>

<p style="text-align: right;">Page 86</p> <p>1 manufacturer of valsartan inspected products for 2 nitrosamines prior to 2018? 3 MR. DAVIS: Objection -- object to the form 4 and object to -- as vague and ambiguous as to the 5 question. 6 You can answer. 7 THE WITNESS: So I'd have to go back and 8 look at documents to see. I may be aware. It's not 9 something I reviewed relative to this particular report. 10 Q. (BY MR. HUNCHUCK) All right. Please take a 11 look at Paragraph 174 of your report. 12 A. Okay. 13 Q. It says here, the FDA told Aurobindo in a 14 warning letter, et cetera, did you review the FDA's 15 Form 483 from the AB site inspection? 16 A. I may have. I'm not certain. If I -- if I 17 did, it would have been in one of the documents in my 18 Exhibit A. 19 Q. Okay. Do you know whether Aurobindo responded 20 in writing to the 483 before FDA issued its warning 21 letter? 22 A. I'm having a difficult time hearing you. So I 23 missed the first part of that. 24 MR. HUNCHUCK: Is there -- is there a way 25 to turn up the volume of my voice in the room or?</p>	<p style="text-align: right;">Page 88</p> <p>1 Do you know whether Aurobindo ever 2 evaluated potential for key starting materials, other 3 raw materials and solvents, to result in the presence of 4 NDMA and NDEA? 5 MR. DAVIS: Object to form. Vague and 6 ambiguous. 7 THE WITNESS: I have no idea whether they 8 evaluated other things. Now again, my -- my focus was 9 on the CGMP deficiencies. It wasn't what they may or 10 may not have evaluated. 11 Q. (BY MR. HUNCHUCK) Do you know if -- strike 12 that. 13 I would like to take a look at 14 Paragraph 175. You say, (Reading:) The fact that 15 Aurobindo could not even competently investigate the 16 nitrosamine contamination once it became a focus of the 17 FDA demonstrates that Aurobindo's quality management 18 system had serious flaws and deficiencies. 19 Did I read that correctly? 20 MR. DAVIS: He's asking if you read 21 Paragraph 175. 22 THE WITNESS: I did read it. 23 Q. (BY MR. HUNCHUCK) Okay. Can you please tell 24 me what the serious flaws were? 25 A. The serious flaws were that the company</p>
<p style="text-align: right;">Page 87</p> <p>1 MR. DAVIS: Yeah, I think it's -- it's as 2 high as it's going to go. 3 Q. (BY MR. HUNCHUCK) Okay. Mr. Quick, do you 4 know whether Aurobindo responded in writing to the 483 5 before FDA issued its warning letter? 6 A. I don't know the answer to that question. My 7 assumption would be that they most likely did, which was 8 what most companies would do, but I don't know. 9 Q. Do you know whether Aurobindo informed FDA of 10 its intent to evaluate the potential for key starting 11 materials, other raw materials and solvents, to result 12 in the presence NDMA and NDEA before the FDA issued its 13 warning letter? 14 A. Again, I'm not sure I had those documents 15 reviewed. So I'm not -- I don't know. I may have, but 16 I don't know. 17 Q. Did you ask to see Aurobindo's response to 18 the 483 report? 19 A. I don't believe I did. But I might have. But 20 the relevant thing is, as I said before, I'm not looking 21 at all the deficiencies, GMP deficiencies. I was just 22 looking at examples, and these are the examples that I 23 have for my report that apply to the entire class. 24 Q. And that -- that's exactly why I'm asking you 25 about these examples you cited in your report.</p>	<p style="text-align: right;">Page 89</p> <p>1 qualified Lantech to recycle solvents without having 2 done a proper investigation, didn't -- didn't understand 3 what they were doing, and had they done that, had the 4 quality management system been in place to do that, we 5 probably wouldn't have had this situation. 6 Q. We're going -- we're going to get to Lantech. 7 But I'm asking about Aurobindo's investigation that you 8 cited in Paragraph 175. 9 So what were the serious flaws in 10 Aurobindo's investigation? You say "serious flaws" and 11 I would like to know what you mean by that. 12 MR. DAVIS: Object to form. Objection, 13 mischaracterizing his report and the testimony. 14 You can answer. 15 THE WITNESS: Okay. The flaws -- the flaws 16 were that they did not do a proper investigation 17 relative to the issue. Had they done that, we would not 18 have had the problem with Lantech. So I -- again, 19 I'm -- I -- I am not going through an exhaustive 20 analysis here. I'm just citing a couple of examples and 21 this goes back -- I know you don't want to talk about 22 Lantech here. But this goes back to the issue with 23 Lantech and the recycled solvents. 24 Q. (BY MR. HUNCHUCK) Do you know how many lots of 25 Aurobindo's products contained NDMA?</p>

<p style="text-align: right;">Page 90</p> <p>1 A. I may have seen that, but that wasn't relevant</p> <p>2 to this report.</p> <p>3 Q. Do you know the level of concentration of NDMA</p> <p>4 found in any of Aurobindo's lots?</p> <p>5 A. I may have seen that someplace, but that was</p> <p>6 not relevant to this report.</p> <p>7 Q. Would you agree that certain laws of</p> <p>8 Aurobindo's VCDs had concentrations of NDA below the</p> <p>9 FDA's acceptable intake level?</p> <p>10 A. They may have. But again, that's not relevant.</p> <p>11 The real issue is the control. So if the company did</p> <p>12 not have adequate control or suppliers did not have</p> <p>13 adequate control and some lots had acceptable limits,</p> <p>14 others did not, would indicate there was a lack of</p> <p>15 control and consistency relative to the product.</p> <p>16 Q. Mr. Quick, in your view, does the presence of a</p> <p>17 detectable amount of nitrosamine in a VCD always</p> <p>18 demonstrate a failure to comply with the CGMP?</p> <p>19 A. I did not opine on that. My point was that</p> <p>20 there were deficiencies --</p> <p>21 Q. I'm asking you -- I'm asking you --</p> <p>22 MR. DAVIS: Don't cut the witness off,</p> <p>23 Steven.</p> <p>24 Q. (BY MR. HUNCHUCK) My apologies. My apologies.</p> <p>25 A. I did not render an opinion on that.</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. (BY MR. HUNCHUCK) What established standard</p> <p>2 applied for comparing Aurobindo's recovered solvent?</p> <p>3 A. Well, it should be the established standard</p> <p>4 that the company had. My quote here from this -- in 72</p> <p>5 is from the API process inspection manual.</p> <p>6 Q. Do you know whether the test Aurobindo used</p> <p>7 would have detected the presence of nitrosamines?</p> <p>8 MR. DAVIS: Object to form. Objection,</p> <p>9 outside the scope. He's not a process chemist.</p> <p>10 You can try and answer if you -- if you</p> <p>11 want.</p> <p>12 THE WITNESS: I don't have an answer for</p> <p>13 that because that's not an area that I reviewed and was</p> <p>14 not part of my report.</p> <p>15 Q. (BY MR. HUNCHUCK) We can go back to the</p> <p>16 Aurobindo specific section. Please look at</p> <p>17 Paragraph 168.</p> <p>18 A. Okay.</p> <p>19 Q. You say, (Reading:) Lantech had not even been</p> <p>20 investigated by the FDA prior to 2018.</p> <p>21 MR. DAVIS: Inspected I believe.</p> <p>22 Q. (BY MR. HUNCHUCK) I'm sorry. Let me strike</p> <p>23 that.</p> <p>24 You say, (Reading:) Lantech had not even</p> <p>25 been inspected by the FDA prior to 2018.</p>
<p style="text-align: right;">Page 91</p> <p>1 Q. As you sit here today, in your view, does the</p> <p>2 presence of a detectable amount of nitrosamine in a VCD</p> <p>3 always demonstrate a failure to comply with a CGMP?</p> <p>4 MR. DAVIS: Object to form. Objection,</p> <p>5 improper hypothetical.</p> <p>6 THE WITNESS: Again, like I said, I did not</p> <p>7 look at that, I did not review that. If we want to do</p> <p>8 that in some further report, we can go down that report,</p> <p>9 but I did not go down that path in my report and I have</p> <p>10 not -- did not review that aspect.</p> <p>11 Q. (BY MR. HUNCHUCK) Will you please take a look</p> <p>12 at Paragraph 72 of your report?</p> <p>13 A. 72?</p> <p>14 MR. DAVIS: 7-2.</p> <p>15 Q. (BY MR. HUNCHUCK) 72, yes. It says,</p> <p>16 (Reading:) FDA expects drug manufacturers to test and</p> <p>17 compare recovered solvents to an established standard.</p> <p>18 Did I read that correctly?</p> <p>19 A. Right, you did.</p> <p>20 Q. What was the solvent Aurobindo recovered?</p> <p>21 MR. DAVIS: Object to form and object to</p> <p>22 the memory test that you're trying to use here.</p> <p>23 THE WITNESS: So I probably saw that, but I</p> <p>24 don't recall that and that was not relevant to my</p> <p>25 report.</p>	<p style="text-align: right;">Page 93</p> <p>1 Did I read that correctly?</p> <p>2 A. You did.</p> <p>3 Q. What is the basis for that opinion?</p> <p>4 A. The basis is I don't -- I don't believe -- in</p> <p>5 fact, they had been inspected prior to that date. I</p> <p>6 believe they came in after this occurred.</p> <p>7 Q. What is -- what assumption are you making for</p> <p>8 that belief?</p> <p>9 MR. DAVIS: Object to form.</p> <p>10 THE WITNESS: I -- I'm not quite certain</p> <p>11 where it came from, but I believe it to be factually</p> <p>12 correct.</p> <p>13 Q. (BY MR. HUNCHUCK) That's -- that's my</p> <p>14 question. Where did that come from?</p> <p>15 A. I don't recall at this point in time where it</p> <p>16 came from. But, I mean, that's something -- go ahead.</p> <p>17 Q. Sorry. I didn't mean to interrupt you. Please</p> <p>18 go ahead.</p> <p>19 A. So I believe that to be a statement of fact,</p> <p>20 but I'm not quite sure where that originated.</p> <p>21 Q. Was Lantech licensed by the FDA?</p> <p>22 MR. DAVIS: Object -- sorry. Object to</p> <p>23 form. Objection, vague and ambiguous.</p> <p>24 You can answer.</p> <p>25 THE WITNESS: Okay. The FDA does not</p>

<p style="text-align: right;">Page 94</p> <p>1 license. The -- the firm has to have a drug 2 establishment. They register as a drug establishment. 3 The FDA does not license them. 4 Q. (BY MR. HUNCHUCK) Okay. In Paragraph -- can 5 you please look at Paragraph 169? 6 A. Okay. 7 Q. You say, (Reading:) Had Aurobindo been 8 properly overseeing Lantech Pharmaceuticals and 9 conducting its appropriate due diligence, Aurobindo 10 would have observed Lantech appeared to be 11 cross-contaminating Aurobindo's solvents recovery 12 activities with other manufacturers. 13 Did I read that correctly? 14 A. You did. 15 Q. Can you please describe Lantech's process for 16 recovering solvents for Aurobindo? 17 MR. DAVIS: Objection, asked and answered. 18 Objection, outside the scope. Objection, he's not a 19 process chemist. I don't see where you're even trying 20 to go with this, Steven. 21 You can answer if you want. 22 THE WITNESS: The issue was not how they do 23 it. The issue was the cross-contamination. 24 Q. (BY MR. HUNCHUCK) You opined that Aurobindo 25 failed to oversee its -- its solvent recovery vendor,</p>	<p style="text-align: right;">Page 96</p> <p>1 Q. Looking back at Paragraph 169, you say 2 "properly overseeing." Can you please tell me the basis 3 for that statement? 4 A. Which -- which paragraph? 5 MR. DAVIS: Which paragraph, Steven? 6 MR. HUNCHUCK: 169. 7 MR. DAVIS: 169. 8 THE WITNESS: Okay. The basis for that is 9 the FDA warning letter and also the deposition that I 10 reference there. 11 Q. (BY MR. HUNCHUCK) Do you know what steps, if 12 any, were taken to oversee Lantech's solvent recovery 13 process? 14 A. I don't know what specific steps were taken. 15 But whatever they were, they were not adequate. 16 Q. Why do you believe Aurobindo would have 17 observed that Lantech appeared to be 18 cross-contaminating? 19 A. That came out in the -- in the warning letters, 20 and like I said before, if, in fact, the company 21 had --had -- properly had oversight and audited and 22 understood what Lantech was doing, the company should 23 have been aware of what they were doing. 24 Q. Do you know what Lantech's solvent's recovery 25 equipment looks like?</p>
<p style="text-align: right;">Page 95</p> <p>1 and I'm trying to understand what you know about 2 Lantech's solvent recovery methods to determine that 3 Aurobindo failed to oversee it. 4 So my question is, please describe 5 Lantech's process for recovering Aurobindo's solvent. 6 MR. DAVIS: Same objections. 7 THE WITNESS: So Lantech's processes are 8 not relevant here. The fact is that they were not -- 9 the proper oversight didn't exist, which appeared in the 10 warning letters. 11 Q. (BY MR. HUNCHUCK) Where were the nitrosamines 12 found at Lantech? 13 A. I don't recall where they were found. 14 MR. DAVIS: Object to form to that question 15 also. 16 THE WITNESS: Again, my -- as I'll say 17 again, my report was covering examples of CGMP 18 deficiencies, and it was clear that the company did not 19 have proper oversight over Lantech. 20 Q. (BY MR. HUNCHUCK) What is your understanding 21 of what caused nitrosamines to be present on Lantech's 22 equipment? 23 A. I did not get into that level of detail. The 24 issue was that there was not proper oversight and this 25 did, in fact, occur.</p>	<p style="text-align: right;">Page 97</p> <p>1 MR. DAVIS: Objection to form. Objection, 2 relevance. 3 THE WITNESS: I have no idea what their 4 equipment looks like. I've never been to Lantech, so 5 I've never seen it. 6 Q. (BY MR. HUNCHUCK) Do you -- in Paragraph 170 7 you say, (Reading:) Lantech's operations were so 8 deficient that cross-contamination was occurring at 9 least in four different ways. 10 What were the four different ways? 11 A. Well, the four different ways were described in 12 the depositions, which if we want to pull those 13 depositions up, we can look at those. 14 Q. Are you familiar with -- I'm going to butcher 15 this name. Apologies. Are you familiar with Tree Can't 16 (phonetic) Road Lines? 17 A. I didn't hear that. 18 MR. DAVIS: Can you -- can you repeat the 19 question? 20 Q. (BY MR. HUNCHUCK) Are you familiar with Tree 21 Can't (phonetic) Road Lines, the trucking company, Tree 22 Can't Road Lines? 23 A. Am I familiar with them? I don't believe so. 24 Q. Are you familiar with Jaganat Road Lines? 25 MR. DAVIS: Objection, relevance.</p>

<p style="text-align: right;">Page 98</p> <p>1 You can answer.</p> <p>2 THE WITNESS: I don't believe I am.</p> <p>3 Q. (BY MR. HUNCHUCK) Have you ever seen</p> <p>4 Lantech -- strike that.</p> <p>5 If we look at Paragraph 171, you say,</p> <p>6 (Reading:) Aurobindo's chief quality officer,</p> <p>7 Dr. Ambati Rama Mohana Rao, would agree that Lantech's</p> <p>8 equipment is being uncleaned.</p> <p>9 Do you know what equipment Mr. Rao was</p> <p>10 referring to?</p> <p>11 A. I don't know specifically what equipment he was</p> <p>12 referring to. This comes from the deposition.</p> <p>13 Q. Do you have an understanding as to what he</p> <p>14 meant by saying "unclean"?</p> <p>15 A. Well, we'd have to go back to the deposition if</p> <p>16 we want to do that, and we could discuss that. But I --</p> <p>17 just looking at this today, I'm not sure. I mean, the</p> <p>18 fact is it wasn't. So...</p> <p>19 Q. Why do you say that?</p> <p>20 A. Because there was cross-contamination.</p> <p>21 Q. Do you know how many lots of Aurobindo's</p> <p>22 products were contaminated by unclean equipment?</p> <p>23 MR. DAVIS: Objection, asked and answered.</p> <p>24 THE WITNESS: I -- I don't know how many</p> <p>25 lots were contaminated. Again, that's not relevant to</p>	<p style="text-align: right;">Page 100</p> <p>1 job of managing and had oversight of Lantech, they would</p> <p>2 have been there, they would under covered the same kinds</p> <p>3 of things that the FDA did before the FDA inspected. So</p> <p>4 they should have been able to have found whatever the</p> <p>5 FDA found.</p> <p>6 Q. Do you know whether any BCD manufacturers, API,</p> <p>7 or API manufacturers were testifying for nitrosamines</p> <p>8 prior to 2018?</p> <p>9 MR. DAVIS: Objection, asked and answered.</p> <p>10 Frank asked that question in exactly the same verbiage.</p> <p>11 THE WITNESS: So we'd have to go back and</p> <p>12 review the documents relative to that particular point.</p> <p>13 And again, that was not relevant to my report.</p> <p>14 MR. HUNCHUCK: That's all the questions I</p> <p>15 have, Mr. Quick.</p> <p>16 THE WITNESS: Thank you.</p> <p>17 EXAMINATION</p> <p>18 Q. (BY MR. ABRAHAM) Morning, sir. My name is</p> <p>19 Eric Abraham. Can you hear me?</p> <p>20 A. I can hear you, yes.</p> <p>21 Q. Great. I'm going to be asking you some</p> <p>22 questions next. I'm at the law firm of Hill Wallack in</p> <p>23 Princeton, New Jersey, and I represent the Hetero Labs</p> <p>24 and Hetero Drugs, defendants in this case. All right?</p> <p>25 A. All right.</p>
<p style="text-align: right;">Page 99</p> <p>1 the CGMP deficiencies. The CGMP deficiency would --</p> <p>2 would pertain to whether they had contaminated a product</p> <p>3 or not. So how many lots would not be relevant to this.</p> <p>4 Q. (BY MR. HUNCHUCK) Are you aware that not all</p> <p>5 of Aurobindo's lots were recalled?</p> <p>6 A. I'm not -- I'm not certain how many lots were</p> <p>7 recalled or whether they weren't recalled. But again,</p> <p>8 that's not relevant to the CGMP deficiencies that I</p> <p>9 found. And again, I state those were just examples.</p> <p>10 Q. Are you aware that certain consumers of</p> <p>11 Aurobindo's valsartan containing drugs did not consume</p> <p>12 any nitrosamines?</p> <p>13 MR. DAVIS: Objection, assumes facts not in</p> <p>14 evidence.</p> <p>15 THE WITNESS: Again, I'm not aware of that,</p> <p>16 and again, it's not relevant to the report that I wrote.</p> <p>17 Q. (BY MR. HUNCHUCK) Okay. In Paragraph 172 you</p> <p>18 say, (Reading:) Had Aurobindo done even a minimal</p> <p>19 amount of due diligence, it could have discovered these</p> <p>20 deficiencies for itself in any of the years prior</p> <p>21 to 2019.</p> <p>22 What was necessary to discover the presence</p> <p>23 of nitrosamines before 2019?</p> <p>24 A. So the paragraph talks about the deficiencies.</p> <p>25 And my point earlier had the company done an adequate</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. Do you still -- still have your report in front</p> <p>2 of you?</p> <p>3 A. I do.</p> <p>4 Q. Okay. Great.</p> <p>5 Please tell me your understanding of the</p> <p>6 role, if any, that Hetero Labs played in the supply of</p> <p>7 valsartan into the United States.</p> <p>8 MR. DAVIS: Object to form.</p> <p>9 THE WITNESS: We'd have to go back -- as we</p> <p>10 talked about, there's been a number of entities here.</p> <p>11 We'd have to go back and review those documents. That</p> <p>12 was not the subject of my report. My subject of my</p> <p>13 report is what I have on Page 35 of the report.</p> <p>14 Q. (BY MR. ABRAHAM) Okay. Let me ask it</p> <p>15 different.</p> <p>16 Do you know whether Hetero Labs was an API</p> <p>17 manufacturer or a finish dose manufacturer of valsartan?</p> <p>18 A. I believe that they're an API manufacturer.</p> <p>19 Q. And do you think that they were a finished dose</p> <p>20 manufacturer? Do you know?</p> <p>21 A. I'm not -- they may be. I'm not sure.</p> <p>22 Q. Okay.</p> <p>23 A. I would have to go back -- I would have to go</p> <p>24 back and review the documents. Again, that's not</p> <p>25 something I opined in the -- in the -- my document, my</p>

<p style="text-align: right;">Page 102</p> <p>1 report.</p> <p>2 Q. Okay. And how about Hetero Drugs, was Hetero</p> <p>3 Drugs an API manufacturer; do you know?</p> <p>4 A. I thought I just -- just answered that.</p> <p>5 Q. Okay. Do you know the difference between</p> <p>6 Hetero Drugs and Hetero Labs as corporate entities?</p> <p>7 A. I -- I have not studied the corporate structure</p> <p>8 of the company.</p> <p>9 Q. Okay. Do you know which one manufactured API</p> <p>10 or which one manufactured finished dose of valsartan?</p> <p>11 MR. DAVIS: Objection, asked and answered.</p> <p>12 He says he hasn't studied the corporate structure of</p> <p>13 Hetero.</p> <p>14 MR. ABRAHAM: Counsel, please don't answer</p> <p>15 for the witness.</p> <p>16 Q. (BY MR. ABRAHAM) Can you tell me what the</p> <p>17 difference is between Hetero Drugs and Hetero Labs with</p> <p>18 respect to the manufacture of valsartan?</p> <p>19 A. No. I cannot tell you the difference. If we</p> <p>20 went back and reviewed some of the documents, maybe I</p> <p>21 could, but that was not the subject of my report.</p> <p>22 Q. Do you know what manufacturing facility, either</p> <p>23 Hetero Drugs or Hetero Labs, produced the valsartan</p> <p>24 APIN?</p> <p>25 A. Which facility?</p>	<p style="text-align: right;">Page 104</p> <p>1 report. I don't believe that was one of the issues that</p> <p>2 I looked at here. Again, my --</p> <p>3 Q. (BY MR. ABRAHAM) Okay.</p> <p>4 A. -- as I said before --</p> <p>5 MR. DAVIS: Hey, hey, Eric, let him finish</p> <p>6 his answer. Thank you.</p> <p>7 MR. ABRAHAM: Answer the question. Thank</p> <p>8 you very much.</p> <p>9 MR. DAVIS: Hang on. Before you move on,</p> <p>10 you've got to let the witness finish his answer. You</p> <p>11 cannot cut him off mid sentence. Thank you.</p> <p>12 MR. ABRAHAM: John, please, stop.</p> <p>13 Q. (BY MR. ABRAHAM) Sir, you haven't offered any</p> <p>14 opinion as to any failure by Hetero to assess deviations</p> <p>15 or unknown peaks or aberrate, correct?</p> <p>16 A. That's correct. I only offered the opinions</p> <p>17 that I offered relevant to the specific deficiencies</p> <p>18 that are in this report. And again, I cite those as</p> <p>19 being examples. There may be others.</p> <p>20 Q. And you offered no opinion about any failure by</p> <p>21 Hetero to adequately validate the valsartan</p> <p>22 manufacturing process change, correct?</p> <p>23 A. Again, as I said, I only offered opinions on</p> <p>24 specific examples. It was not an exhaustive analysis of</p> <p>25 the issues.</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Yes, sir.</p> <p>2 A. I'm not certain. But that -- I'm sure that was</p> <p>3 probably on the 43. I -- that wasn't relevant, this</p> <p>4 particular document, to put which facility.</p> <p>5 Q. Sir, I don't want to hear about your position</p> <p>6 about what's relevant --</p> <p>7 MR. DAVIS: He's entitled -- hang on, Eric,</p> <p>8 he's entitled to his testimony.</p> <p>9 MR. ABRAHAM: Don't interrupt me. I have</p> <p>10 very little time. Don't interrupt me.</p> <p>11 Q. (BY MR. ABRAHAM) My next question, sir: Do</p> <p>12 you know what Hetero facility manufactured the valsartan</p> <p>13 finished dose?</p> <p>14 A. I probably do. Okay. Well -- the finished</p> <p>15 dose, I'm not certain.</p> <p>16 Q. Okay. Now, if I look at your report, it looks</p> <p>17 to me like Paragraphs 176 through 186 are the paragraphs</p> <p>18 that are specific to Hetero; is that correct?</p> <p>19 A. That is correct.</p> <p>20 Q. You offered no opinion as to any alleged</p> <p>21 failure by Hetero to conduct a risk assessment</p> <p>22 associated with any manufacturing change for valsartan</p> <p>23 and API, correct?</p> <p>24 MR. DAVIS: Object to form.</p> <p>25 THE WITNESS: Let me just look back at the</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. So your expert report focused on two Form 483s</p> <p>2 that were issued to Hetero, correct?</p> <p>3 A. I believe that to be the case. But we'd have</p> <p>4 to go back and --</p> <p>5 Q. Those are the only things that you footnoted --</p> <p>6 MR. DAVIS: Eric, let him finish his answer</p> <p>7 before moving onto your next question.</p> <p>8 THE WITNESS: I believe that to be the</p> <p>9 case. The documents that I referenced are the ones in</p> <p>10 the footnotes at the bottom of the page.</p> <p>11 Q. (BY MR. ABRAHAM) Right. And those -- the only</p> <p>12 footnotes are to the two Form 483s, right?</p> <p>13 A. I believe that to be the case.</p> <p>14 Q. Okay. I have emailed to your counsel,</p> <p>15 Ms. Hilton, copies of those two Form 483s. So if I</p> <p>16 could ask her to please hand those to you so that way if</p> <p>17 we need to refer to them during the questioning, you'll</p> <p>18 have them. Okay?</p> <p>19 MR. DAVIS: Sure. I am handing them to the</p> <p>20 court reporter to be marked as exhibits.</p> <p>21 MR. ABRAHAM: Great. And if the court</p> <p>22 reporter could just mark the March 2018 Form 483 and the</p> <p>23 September 28 Form 483 and just let me know what numbers</p> <p>24 you affix to those.</p> <p>25 MR. DAVIS: Okay. The March one will</p>

<p style="text-align: right;">Page 106</p> <p>1 first.</p> <p>2 (Exhibits No. 30 and 31 were marked.)</p> <p>3 MR. DAVIS: For the record, the witness has</p> <p>4 the March 483 as Exhibit 30 and the September as</p> <p>5 Exhibit 31.</p> <p>6 Q. (BY MR. ABRAHAM) Great. Sir, if you could</p> <p>7 just confirm for me, do you see Bates numbers on the</p> <p>8 bottom of Exhibit 30? It should say Hetero USA with</p> <p>9 some numbers?</p> <p>10 A. I do.</p> <p>11 Q. Okay. It's Hetero USA151204 on the first page?</p> <p>12 A. I do.</p> <p>13 Q. Okay. And it goes through -- the last number</p> <p>14 ends with the Bates number 7, correct?</p> <p>15 A. Yes, that's correct.</p> <p>16 Q. Okay. And then for Exhibit 31 it's got the</p> <p>17 Bates number HLL446173 on the bottom right corner,</p> <p>18 right?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. And the very last page, it ends</p> <p>21 with 446176, correct?</p> <p>22 A. 179?</p> <p>23 Q. Oh, it goes through 179? Okay.</p> <p>24 A. Yes.</p> <p>25 Q. Thank you.</p>	<p style="text-align: right;">Page 108</p> <p>1 A. I don't believe that I had those.</p> <p>2 Q. Of the -- the February and March of 2018</p> <p>3 inspection, that occurred a few months before the</p> <p>4 manufacture of the valsartan by Hetero that allegedly</p> <p>5 contained the NDMA impurity; is that correct?</p> <p>6 A. If you're asking did this occur before the ZHP</p> <p>7 in the situation of June of 2018, is that what you're</p> <p>8 asking?</p> <p>9 Q. No, my question was specifically to Hetero.</p> <p>10 Not ZHP, sir.</p> <p>11 A. Okay.</p> <p>12 MR. DAVIS: Perhaps you can repeat the</p> <p>13 question.</p> <p>14 Q. (BY MR. ABRAHAM) My question is whether this</p> <p>15 inspection that's referenced in Exhibit 30 took place</p> <p>16 before the manufacture of allegedly impure valsartan by</p> <p>17 Hetero.</p> <p>18 MR. DAVIS: Object to form.</p> <p>19 Q. (BY MR. ABRAHAM) Do you know?</p> <p>20 A. I'm not certain I really understand what you're</p> <p>21 asking.</p> <p>22 Q. Okay. If you don't understand my question, say</p> <p>23 so.</p> <p>24 Do you know when it is that Hetero is</p> <p>25 alleged to have manufactured valsartan with an NDMA</p>
<p style="text-align: right;">Page 107</p> <p>1 These Form 483s were issued by the FDA at</p> <p>2 Hetero in conclusion of facility inspections that are</p> <p>3 referenced in the upper right-hand corner of Form 483,</p> <p>4 right?</p> <p>5 A. I missed the last part of that.</p> <p>6 Q. The dates of inspection for each Form 483 are</p> <p>7 notated in the upper right-hand corner, correct?</p> <p>8 A. That's correct.</p> <p>9 Q. So those inspections occurred in late February</p> <p>10 and early March of 2018 and then a second series of</p> <p>11 inspections in September of 2018; is that correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Other than these two Form 483s, did you rely on</p> <p>14 anything else to reach your conclusions that you reached</p> <p>15 as against Hetero in your declaration that's marked as</p> <p>16 Exhibit 6?</p> <p>17 A. Again, I'd have to go back and look at all</p> <p>18 these footnotes to make sure that these footnotes that I</p> <p>19 reference here didn't include any other documents. But</p> <p>20 I'm not certain because we haven't -- I haven't pulled</p> <p>21 those up.</p> <p>22 Q. Okay. Did you review any of the FDA's</p> <p>23 establishment inspection reports for the Hetero</p> <p>24 manufacturing facility that's the subject of Exhibit 30,</p> <p>25 the Form 483 from -- from March 2018?</p>	<p style="text-align: right;">Page 109</p> <p>1 impurity present?</p> <p>2 A. I'm not certain. There may have been</p> <p>3 documents, but I'm just not certain here today.</p> <p>4 Q. Okay. Did you evaluate or consider whether FDA</p> <p>5 had determined that the Hetero manufacturing facility</p> <p>6 was in an acceptable state of compliance with CGMP as of</p> <p>7 February and March of 2018?</p> <p>8 A. As you indicated, the documents that I reviewed</p> <p>9 were the FDA 483 reports.</p> <p>10 Q. I understand that. But I want to know whether</p> <p>11 you did anything to determine whether FDA had determined</p> <p>12 that the facility was in an acceptable state of</p> <p>13 compliance with CGMP as of the February and March 2018</p> <p>14 timeframe?</p> <p>15 A. I'm not sure there are any other documents to</p> <p>16 review. Had I -- if the documents were there, I'd be</p> <p>17 glad to review them.</p> <p>18 Q. I'm not asking you to do something now. I'm</p> <p>19 wondering what you did to form your opinion. In other</p> <p>20 words, did you or did you not determine whether FDA had</p> <p>21 reached the conclusion about whether the facility</p> <p>22 subject to Exhibit 30 was in compliance with CGMP as of</p> <p>23 February and March 2018? If you did, you did. If you</p> <p>24 didn't, you didn't. Just tell me.</p> <p>25 A. So in order to do that, we probably would have</p>

<p style="text-align: right;">Page 110</p> <p>1 had to seen the EIRs from prior inspections where they</p> <p>2 probably would state that. I have not seen those.</p> <p>3 Q. Okay. So you didn't look at the EIRs either</p> <p>4 before or after March 2018 for Hetero, is that fair?</p> <p>5 A. Well, it's fair, but I don't think they were</p> <p>6 provided. Had they been provided, I would have reviewed</p> <p>7 them.</p> <p>8 Q. Okay. But they weren't provided by the lawyers</p> <p>9 who retained you, right?</p> <p>10 A. Again, I'm not certain. If they have them,</p> <p>11 they may have been provided, but I just don't recall</p> <p>12 reviewing those.</p> <p>13 Q. Okay. So in other words, the lawyers that</p> <p>14 retained you may have made a choice not to share those</p> <p>15 documents?</p> <p>16 MR. DAVIS: Objection, that</p> <p>17 mischaracterizes his testimony.</p> <p>18 THE WITNESS: That's not what I said.</p> <p>19 Q. (BY MR. ABRAHAM) Okay. You told me that you</p> <p>20 hadn't been provided with those documents, correct?</p> <p>21 A. I'm not even sure that I asked for them. So...</p> <p>22 Q. Okay.</p> <p>23 A. The bottom line is I have -- I have not seen</p> <p>24 those. To answer your question whether it'd been in</p> <p>25 compliance, I don't know because I haven't seen the</p>	<p style="text-align: right;">Page 112</p> <p>1 inspection?</p> <p>2 A. I don't believe I've seen that.</p> <p>3 Q. Isn't the normal process for the recipient of a</p> <p>4 Form 483 to respond?</p> <p>5 A. It is.</p> <p>6 Q. Do you know whether Hetero responded to</p> <p>7 the Form 483s that were issued in March and September</p> <p>8 of 2018?</p> <p>9 A. I don't know, but I assume they probably did.</p> <p>10 Most companies would respond.</p> <p>11 Q. So in issuing your declaration, you didn't</p> <p>12 review any responses that Hetero may have made to those</p> <p>13 Form 483s, right?</p> <p>14 A. Had I seen those, I would have reviewed them.</p> <p>15 Q. Right. Did you ask for them?</p> <p>16 A. I don't recall whether I asked for them or not.</p> <p>17 Q. Wasn't it important to you to consider the</p> <p>18 responses of Hetero to the Form 483s issued in March and</p> <p>19 September of 2018 before you issued your declaration?</p> <p>20 A. No. As I said before, my examples are only</p> <p>21 examples. It's not exhaustive. If this were a merits</p> <p>22 report, that's one thing I would absolutely do. But</p> <p>23 this is not a merits report. These are examples of CGMP</p> <p>24 deficiencies.</p> <p>25 Q. Okay. But the Form 483s, they are not final</p>
<p style="text-align: right;">Page 111</p> <p>1 document that would say one way or the other.</p> <p>2 Q. And you didn't ask for them, correct?</p> <p>3 A. Well, I don't -- I don't know. I would have to</p> <p>4 go back and see what it asked for originally.</p> <p>5 Q. Okay. And you weren't provided them. We can</p> <p>6 agree on that?</p> <p>7 A. Well, I don't know. I am not sure what was</p> <p>8 provide and what wasn't. I'd have to go back and check.</p> <p>9 Q. Okay. They're not listed on your exhibit to</p> <p>10 your expert report as materials that you reviewed in</p> <p>11 connection with the report, correct?</p> <p>12 A. If they're not there, then I did not review</p> <p>13 them.</p> <p>14 Q. Okay. Did you determine the existence of any</p> <p>15 inspectional classification for the Hetero unit that</p> <p>16 manufactured valsartan API in 2018 such as a no action</p> <p>17 indicated or a voluntary action indicated as of February</p> <p>18 or March of 2018?</p> <p>19 A. I did not review that. But if I were to pursue</p> <p>20 this beyond this, I -- that's one of the things that I</p> <p>21 would do. Again, as I said, my list of examples were</p> <p>22 only examples. They're not exhaustive in terms of the</p> <p>23 situation.</p> <p>24 Q. Okay. And did you review any correspondence to</p> <p>25 Hetero from FDA that followed the February or March 2018</p>	<p style="text-align: right;">Page 113</p> <p>1 agency action, right?</p> <p>2 A. That is correct.</p> <p>3 Q. Okay. So by forming your opinions based just</p> <p>4 upon the Form 483, isn't that sort of like only looking</p> <p>5 at one side of the equation and not the other in</p> <p>6 reaching your conclusion?</p> <p>7 MR. DAVIS: Object to form. Object to the</p> <p>8 analogy.</p> <p>9 THE WITNESS: I'm looking at what the FDA</p> <p>10 saw when they inspected the facility and what they had</p> <p>11 as observations. Again, I would review the other</p> <p>12 documents that you've referred to if this were to</p> <p>13 continue to a merits report, and I agree that those</p> <p>14 documents would be documents that I would review in that</p> <p>15 situation.</p> <p>16 Q. (BY MR. ABRAHAM) Okay. And you offered your</p> <p>17 declaration without even reading the transcript of a</p> <p>18 single Hetero witness, correct?</p> <p>19 A. I don't believe so.</p> <p>20 Q. You don't believe so meaning you didn't review</p> <p>21 any Hetero Labs depositions, correct?</p> <p>22 A. I don't believe that I did. I reviewed a</p> <p>23 number of documents. If they're not in my Exhibit A,</p> <p>24 then I did not review those.</p> <p>25 Q. Okay. Let's talk about the Form 483s that you</p>

<p style="text-align: right;">Page 114</p> <p>1 did cite in the report. And I'd like you to start with 2 the March 2, 2018 Form 483 which we've marked as 3 Exhibit 30. Do you have that in front of you? 4 A. I do. 5 Q. Great. Did you review any communication 6 between Hetero and FDA regarding the manufacturing 7 changes that allegedly gave rise to the NDMA purity of 8 valsartan API? 9 A. I don't believe so. And if it's not referenced 10 in my Exhibit A, then I probably did not review those. 11 Q. Okay. The March 2018 Form 483 identified five 12 observations, correct? 13 A. Yes, there are five observations. 14 Q. And the Form 483 doesn't indicate that any of 15 those five observations actually caused the NDMA 16 impurity to arise in Hetero's valsartan API, correct? 17 A. Correct, but I wouldn't expect to see that 18 anyway. 19 Q. You don't offer the opinion that any 20 observations contained in the March 2018 Form 483 21 actually caused the alleged NDMA impurity to arise in 22 Hetero's valsartan API, correct? 23 MR. DAVIS: Let me object just to -- in the 24 sense that this document is heavily redacted. 25 But you can answer.</p>	<p style="text-align: right;">Page 116</p> <p>1 Q. (BY MR. ABRAHAM) Do you need it repeated, sir? 2 A. No. I heard the question. But my -- my -- my 3 point was, what I was going to say is I'm not aware of 4 specific dates relative to specifications or standards 5 or whatever as it relates to this. I'd have to go back 6 and -- I'd have to go back and review what those are. 7 But again, that was not relevant to my report. 8 Q. As far as you know today, was there a USP 9 monograph that required testing for NDMA as of 10 March 2018? 11 MR. DAVIS: Object to form. 12 THE WITNESS: See, again, no. But again, I 13 may have seen those documents but I -- those were not 14 relevant to my report. 15 Q. (BY MR. ABRAHAM) Okay. Again, I'd like to 16 look at the specifics briefly. 17 The first observation in the Exhibit 30 18 Form 483 relates to a thorough review of an unexplained 19 discrepancy between a batch and some specs, correct? 20 A. Well, it's very heavily redacted. I mean, I 21 can read what the unredacted part is. 22 Q. Right. And that's what the unredacted part 23 says, right, the observation relates to an unexplained 24 discrepancy, correct? 25 A. That's what -- that's what the -- that's what</p>
<p style="text-align: right;">Page 115</p> <p>1 THE WITNESS: Right. That was the point I 2 was going to make as well. Most -- most of the 3 observations are redacted to the point it's not clear. 4 So I would assume the FDA did not make that connection, 5 but it's not clear because of the redactions. 6 Q. (BY MR. ABRAHAM) Right. But you don't offer 7 any opinion on the ultimate question of whether the 8 observations contained in the Form 483 from March 2018 9 actually gave rise to the NDMA impurity in Hetero's 10 valsartan, right? 11 A. That's correct. What I was offering opinions 12 on was the CGMP compliance. 13 Q. Okay. So in other words, but -- but you don't 14 connect the dots; in other words, you don't offer the 15 opinion that any CGMP compliance issues that you 16 identified for Hetero actually gave rise to the NDMA 17 impurity allegedly found in Hetero valsartan, right? 18 A. Right. And that was outside the scope of the 19 report. The report was identified examples of CGMP 20 issues that might pertain to the class. 21 Q. Okay. As of March of 2018, there was no 22 specification for NDMA levels in valsartan APIs; is that 23 correct? 24 MR. DAVIS: Can you repeat that, Eric? I 25 think we both missed that question.</p>	<p style="text-align: right;">Page 117</p> <p>1 the top part of it says, and they go into the example, 2 yes. 3 Q. Okay. And you don't offer the opinion that 4 that discrepancy is what gave rise to the NDMA impurity 5 alleged in the -- 6 A. No. 7 Q. -- valsartan from Hetero, correct? 8 MR. DAVIS: Object to form. 9 THE WITNESS: No. And I stated this 10 before, that was not -- 11 Q. (BY MR. ABRAHAM) You've answered the question, 12 sir. Thank you. 13 MR. DAVIS: Hey, Eric as a professional -- 14 as a professional courtesy, you need to let the witness 15 answer -- finish his answer. 16 MR. ABRAHAM: John, I have a very short 17 amount of time. 18 MR. DAVIS: That does not -- that does not 19 obviate -- 20 MR. ABRAHAM: Don't interrupt me, John. 21 Don't interrupt me. He answers the question -- 22 MR. DAVIS: You need to not interrupt the 23 witness, Eric. 24 Q. (BY MR. ABRAHAM) Sir, I would like to draw 25 your attention to observation No. 2. Observation No. 2</p>

<p style="text-align: right;">Page 118</p> <p>1 relates to responsibilities and procedures applicable 2 for the quality control unit not being followed. Do you 3 see that? 4 A. I see that. 5 Q. And you don't offer the opinion that that's 6 what caused the NDMA to arise in Hetero's valsartan, 7 right? 8 A. No, it goes back to the questions I answered 9 previously -- 10 Q. Okay. Thank you. 11 MR. DAVIS: Let me just -- I'm going to 12 place a formal running objection on the record to the 13 continued interrupting of the witness before he finishes 14 his answers. 15 MR. ABRAHAM: And I'm going to place an 16 objection to the witness's having to answer the 17 questions by giving a speech. So please just confine 18 yourself to answering my question. You can talk to your 19 lawyer afterwards and tell him whatever else you want to 20 tell him. 21 Q. (BY MR. ABRAHAM) I would like to draw your 22 attention, please, to the third observation. This 23 relates to some allegations regarding the lack of 24 training and experience for some employees involved in 25 the processing holding and testing the drug problem,</p>	<p style="text-align: right;">Page 120</p> <p>1 me just place an objection. This is outside the scope. 2 He's not offering any opinion about how nitrosamine is 3 actually formed in these products. 4 You can answer. 5 THE WITNESS: Again, same answer as before. 6 Q. (BY MR. ABRAHAM) Thank you. Now I would like 7 to turn your attention, please, to Exhibit 31. That's 8 the September 2018 Form 483. Do you have that in front 9 of you, sir? 10 A. I do. 11 Q. Okay. Do you understand that this Form 483 12 occurred in the month or so after FDA's recall of 13 Hetero's valsartan? 14 A. So I see it's September. Relative to that 15 sequence of timing, I'm not certain. 16 Q. So you don't know the dates when Hetero's 17 valsartan was recalled; is that correct? 18 A. Well, I probably do. I probably looked at it. 19 But I don't recall those dates in conjunction with this 20 particular inspection. So I don't want to give an 21 answer without going back and checking the exact dates. 22 Q. Okay. What would you go back and check? 23 A. Well, the dates that -- you asked the timing 24 relative to the recall, I'd have to go back and 25 determine when the recall was, and then I could answer</p>
<p style="text-align: right;">Page 119</p> <p>1 correct? 2 A. Correct. 3 Q. So this has to do with some interviews that 4 were conducted by QC personnel within the manufacturing 5 unit by FDA's inspector, right? 6 A. It appears to be the case. 7 Q. And you don't offer the opinion that that's 8 what caused the NDMA to arise allegedly, right? 9 A. Same answer as I have given before. I don't 10 offer that for any of these. 11 Q. Thank you. Observation No. 4 has to do with 12 the equipment used in the production about being 13 maintained in proper conditions. Do you see that? 14 A. I do see that. 15 Q. Okay. And same answer as before, in other 16 words, you didn't offer any opinion that this is what 17 caused the NDMA to arise, correct? 18 A. That is correct. 19 Q. Okay. And the last observation has to do with 20 storage of glassware in a storage area, right? 21 A. Right. 22 Q. Okay. And same answer, that's not what gave 23 rise -- or you don't offer the opinion that that's what 24 gave rise to the NDMA -- 25 MR. DAVIS: Before the witness answers, let</p>	<p style="text-align: right;">Page 121</p> <p>1 your question about whether it was before or after. 2 Q. Well, I want to know is that something that you 3 think you already know the answer to and you just forgot 4 it or that's an answer you would have to go learn? 5 A. It wasn't relevant to my report in terms of 6 CGMP deficiencies. So if you're asking me that 7 question, I need go back and determine when the recall 8 was, and I could determine whether this was before or 9 after. That's the question you're asking me. 10 Q. Okay. Let's look at Exhibit 31. This offers 11 four observations relative to the inspection that was 12 conducted September 17th through the 28th, correct? 13 A. Yes, sir, four observations. 14 Q. Okay. And the Form 483 that's marked as 15 Exhibit 31 that doesn't indicate that any of those four 16 observations actually caused the NDMA impurity to arise 17 in Hetero's valsartan API, correct? 18 MR. DAVIS: Do you need a few moments to 19 review the document? 20 THE WITNESS: I probably need to read this 21 if you want me the answer that. 22 Q. (BY MR. ABRAHAM) Well, you read it before you 23 offered your opinion, right? 24 A. That's been some time ago. 25 Q. But you did read it, right?</p>

<p style="text-align: right;">Page 122</p> <p>1 A. I did.</p> <p>2 Q. Okay. And in your expert report you wrote that</p> <p>3 none of the observations -- well, you didn't offer the</p> <p>4 opinion that any of the observations contained in the</p> <p>5 September 28th Form 483 actually caused the alleged NDMA</p> <p>6 impurity to arise, correct?</p> <p>7 A. That's correct. And that was not within the</p> <p>8 scope of my report.</p> <p>9 Q. Okay. So you stand by that opinion, correct?</p> <p>10 A. I do.</p> <p>11 Q. Okay. Let's look at the specific observations.</p> <p>12 Observation No. 1 relates to the quality control unit</p> <p>13 failed to perform a thorough investigation. Do you see</p> <p>14 that?</p> <p>15 A. I do.</p> <p>16 Q. That's an observation that relates to the</p> <p>17 investigation performed by Hetero after the impurity was</p> <p>18 discovered allegedly in Hetero's product, correct?</p> <p>19 MR. DAVIS: Do you want -- you're asking,</p> <p>20 Eric, about two-and-a-half pages of single space type.</p> <p>21 I think the witness --</p> <p>22 MR. ABRAHAM: John, if you want to make an</p> <p>23 objection, make it. Okay. He just told me he reviewed</p> <p>24 this document in preparation for his deposition. I</p> <p>25 would just like to confirm his understanding.</p>	<p style="text-align: right;">Page 124</p> <p>1 or an OAI?</p> <p>2 A. I'm not certain. I've not reviewed those.</p> <p>3 Q. Okay. Are you aware of any official action</p> <p>4 that was taken by FDA as a result of the Form 483s that</p> <p>5 you relied on in this report?</p> <p>6 A. Again, I did not review those.</p> <p>7 Q. So you don't know if there's a warning letter?</p> <p>8 MR. DAVIS: Eric, the -- Eric, the</p> <p>9 videographer has indicated that he needs to go off the</p> <p>10 record to change the tape.</p> <p>11 MR. ABRAHAM: Okay. We can go off the</p> <p>12 record and do that. Thank you.</p> <p>13 VIDEOGRAPHER: Off the record 11:20 a m.</p> <p>14 (Off the record.)</p> <p>15 VIDEOGRAPHER: We are back on the</p> <p>16 record 11:24 a m.</p> <p>17 MR. DAVIS: For the record, there is 54</p> <p>18 minutes remaining.</p> <p>19 MR. ABRAHAM: Thank you. Just to the</p> <p>20 videographer, our witness is very blurry. Okay. There</p> <p>21 you go. Thank you.</p> <p>22 Q. (BY MR. ABRAHAM) Sir, I just have a few more</p> <p>23 questions, and I appreciate your patience.</p> <p>24 Are you aware of any warning letter or</p> <p>25 import ban that was issued by FDA to Hetero as a result</p>
<p style="text-align: right;">Page 123</p> <p>1 MR. DAVIS: Do you need a few moments</p> <p>2 to read Observation 1?</p> <p>3 (Cross-talk.)</p> <p>4 THE WITNESS: If you want me to answer that</p> <p>5 question, I need to review this today because you're</p> <p>6 asking me a question specifically about the 483.</p> <p>7 Q. (BY MR. ABRAHAM) Okay. Great. Go ahead. And</p> <p>8 let me know when you're done.</p> <p>9 A. Okay.</p> <p>10 MR. GOLDBERG: May I suggest that we go off</p> <p>11 the record because --</p> <p>12 MR. ABRAHAM: No, Seth, you may not suggest</p> <p>13 that because y'all pitched a fit about that when your</p> <p>14 witnesses were spending 20 minutes reading a document.</p> <p>15 So we will not go off the record.</p> <p>16 Q. (BY MR. ABRAHAM) You know what? I'll ask</p> <p>17 another question because I don't want to waste the time</p> <p>18 it will take you to refresh you -- yourself on what the</p> <p>19 contents of that document are.</p> <p>20 Are you familiar with what FDA action</p> <p>21 resulted from the March 2018 or the September 2018 483's</p> <p>22 issue to Hetero?</p> <p>23 A. I've not seen the actions. If there were any</p> <p>24 actions, I've not seen those.</p> <p>25 Q. So you don't if there was an NAI issue or a VAI</p>	<p style="text-align: right;">Page 125</p> <p>1 of the Form 483s that we've been reviewing this morning?</p> <p>2 A. I'm not aware of any.</p> <p>3 Q. Any seizure or regulatory meeting or</p> <p>4 recommendations to cease manufacturing?</p> <p>5 A. I'm not aware of any.</p> <p>6 Q. Okay. Are you aware of any corrective and</p> <p>7 preventive actions or cappas (phonetic) relating to the</p> <p>8 observations of the two Form 483s that we've been</p> <p>9 discussing?</p> <p>10 A. I'm not aware of any because I have not seen</p> <p>11 what the company may have done relative to the 483.</p> <p>12 Q. Okay. So did you review any cappas that were</p> <p>13 initiated in connection with the Form 483s that we've</p> <p>14 been discussing?</p> <p>15 A. I would -- if I had seen them, I would review</p> <p>16 them.</p> <p>17 Q. Did you ask to review them?</p> <p>18 A. I didn't ask to review them because I didn't</p> <p>19 know any had been generated.</p> <p>20 MR. ABRAHAM: Okay. Okay. I am concluded</p> <p>21 with my questions. I appreciate your patience, sir.</p> <p>22 THE WITNESS: Thank you.</p> <p>23 MR. ABRAHAM: What I would like to do is</p> <p>24 ask that we take a very short break so that I can confer</p> <p>25 with my co-counsel. I think we have one questioning</p>

<p style="text-align: right;">Page 126</p> <p>1 lawyer left to go.</p> <p>2 John, can we take a very short break?</p> <p>3 MR. DAVIS: Okay. All right.</p> <p>4 VIDEOGRAPHER: Off the record 11:25 a m.</p> <p>5 (Brief recess.)</p> <p>6 VIDEOGRAPHER: Back on the record. The</p> <p>7 time is 11:34 a m.</p> <p>8 EXAMINATION</p> <p>9 Q. (BY MS. NAGLE) Hi, Mr. Quick. My name is</p> <p>10 Brittney Nagle, and I represent Torrent Pharmaceuticals,</p> <p>11 Ltd. and Torrent Pharma, Inc.</p> <p>12 Have you ever heard -- and I may refer to</p> <p>13 them together as Torrent. Is that fair?</p> <p>14 A. You're asking if I've heard of Torrent?</p> <p>15 Q. I was asking for clarification. When I refer</p> <p>16 to Torrent, I'm referring to those two entities. Okay?</p> <p>17 A. What were the two entities again?</p> <p>18 Q. Torrent Pharmaceuticals, Ltd. and Torrent</p> <p>19 Pharma, Inc.</p> <p>20 A. I would generally just refer to the one.</p> <p>21 Q. By "the one" do you mean Torrent</p> <p>22 Pharmaceuticals, Ltd.?</p> <p>23 A. I would not have made a distinction is what I'm</p> <p>24 saying.</p> <p>25 Q. Okay. Well, you understand there's two</p>	<p style="text-align: right;">Page 128</p> <p>1 products that Torrent manufactures?</p> <p>2 A. Prior to the engagement? I may have, but it's</p> <p>3 not something I had particularly understood or had an</p> <p>4 interest to understand.</p> <p>5 Q. Okay. So when you say you may have, do you</p> <p>6 mean just in your familiarity with the pharmaceutical</p> <p>7 industry?</p> <p>8 A. Well, what I'm saying is you asked the question</p> <p>9 about Torrent's products prior to this engagement. It's</p> <p>10 very possible that I may have. I don't recall.</p> <p>11 Q. Okay. So sitting here today, you don't recall</p> <p>12 knowing anything about what kind of products Torrent</p> <p>13 manufactures prior to being engaged in this matter?</p> <p>14 A. That's not exactly what I said. I may have,</p> <p>15 but I'm not aware that I was.</p> <p>16 Q. Okay. And prior to this engagement, you didn't</p> <p>17 have any understanding of the relationship between</p> <p>18 Torrent and any of its suppliers, correct?</p> <p>19 MR. DAVIS: Object to form.</p> <p>20 THE WITNESS: I don't believe so.</p> <p>21 Q. (BY MS. NAGLE) Okay. Prior to your</p> <p>22 engagement, you hadn't done any analysis of Torrent's</p> <p>23 quality assurance program, correct?</p> <p>24 A. I don't believe so unless it was in connection</p> <p>25 with something else unrelated to this. But I don't</p>
<p style="text-align: right;">Page 127</p> <p>1 different entities?</p> <p>2 A. Okay.</p> <p>3 Q. All right. Do you have any understanding about</p> <p>4 the difference between the two entities?</p> <p>5 MR. DAVIS: Object to form.</p> <p>6 THE WITNESS: I may, but that was not part</p> <p>7 of my review.</p> <p>8 Q. (BY MS. NAGLE) Okay. Had you -- have ever</p> <p>9 heard of Torrent prior to being engaged in this matter?</p> <p>10 A. I'm sure I have.</p> <p>11 Q. Have you ever done any work for Torrent?</p> <p>12 A. No, I have not.</p> <p>13 Q. So safe to say you've never physically been to</p> <p>14 a Torrent facility?</p> <p>15 A. I don't believe so unless there was some sort</p> <p>16 of an acquisition that Torrent had and I might have been</p> <p>17 in a facility where they acquired. But I'm not aware of</p> <p>18 that.</p> <p>19 Q. Are you aware of any instances where you've</p> <p>20 been adverse to Torrent in another engagement?</p> <p>21 MR. DAVIS: Object to form.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: No. I'm sorry. No.</p> <p>24 Q. (BY MS. NAGLE) So prior to your engagement,</p> <p>25 did you have any understanding about the types of</p>	<p style="text-align: right;">Page 129</p> <p>1 believe so.</p> <p>2 Q. Okay. So there's a possibility, but sitting</p> <p>3 here today, you can't think of specifically any</p> <p>4 engagement that would have required you to -- to know</p> <p>5 anything about Torrent's quality assurance program?</p> <p>6 A. I don't believe so, as I said.</p> <p>7 Q. Okay. So -- so as far as you know, as far as</p> <p>8 you can remember, the totality of your understanding of</p> <p>9 Torrent's quality assurance process is based on</p> <p>10 documents that you've reviewed in connection with this</p> <p>11 engagement, correct?</p> <p>12 MR. DAVIS: Object to form.</p> <p>13 THE WITNESS: I believe so.</p> <p>14 Q. (BY MS. NAGLE) Okay. And your understanding</p> <p>15 of the relationship between Torrent and ZHP is based</p> <p>16 entirely on the documents you reviewed in connection</p> <p>17 with this engagement, correct?</p> <p>18 A. That is correct.</p> <p>19 Q. So in your report, looking specifically at</p> <p>20 Paragraph 157, you reached the conclusion that Torrent</p> <p>21 failed to diligently inspect the manufacturing process</p> <p>22 prior to retaining ZHP as its API manufacturer, right?</p> <p>23 A. Right.</p> <p>24 Q. What do you mean comprehensive chemical</p> <p>25 analysis?</p>

<p style="text-align: right;">Page 130</p> <p>1 MR. DAVIS: Where are you referring to,</p> <p>2 Brittny?</p> <p>3 THE WITNESS: Can you refer me to the</p> <p>4 paragraph you're talking from?</p> <p>5 Q. (BY MS. NAGLE) Oh, sorry. I -- I misquoted</p> <p>6 part of your report. I apologize.</p> <p>7 In Paragraph 159, that's -- that's where</p> <p>8 I'm reading that from. I apologize.</p> <p>9 So in Paragraph 159 you wrote, (Reading:)</p> <p>10 Torrent also made no inquiries into the manufacturing</p> <p>11 process uses -- I think that should be used by ZHP and</p> <p>12 failed to conduct a comprehensive chemical analysis.</p> <p>13 Do you see that?</p> <p>14 A. I do see that.</p> <p>15 Q. Can you tell me what you meant by</p> <p>16 "comprehensive chemical analysis"?</p> <p>17 A. Well, it goes to some of the other aspects of</p> <p>18 this section on Torrent, and it relates to the</p> <p>19 depositions that I reviewed.</p> <p>20 Q. Okay. What would you require for a</p> <p>21 comprehensive chemical analysis?</p> <p>22 A. I wouldn't require anything. I'm just saying I</p> <p>23 don't believe that they did.</p> <p>24 Q. What is the basis for that?</p> <p>25 A. I'm just saying based on the depositions that I</p>	<p style="text-align: right;">Page 132</p> <p>1 that ZHP used to make the product that they are</p> <p>2 requiring from ZHP, however they do it, whether it's DMF</p> <p>3 or on-site visits looking at the documents, whatever.</p> <p>4 Q. (BY MS. NAGLE) Well, Mr. Quick, you understand</p> <p>5 that -- that the process API -- the process ZHP uses to</p> <p>6 manufacture its API contains proprietary information,</p> <p>7 correct?</p> <p>8 A. I hear what you said. But my point is that the</p> <p>9 drug manufacturer such as Torrent should have audited.</p> <p>10 They should have gotten complete information relative to</p> <p>11 how the product -- how the API is made.</p> <p>12 Q. So it's your position that a finish dose</p> <p>13 manufacturer is entitled to all proprietary information</p> <p>14 for APIs that it sources?</p> <p>15 MR. DAVIS: Object to form. Object to</p> <p>16 mischaracterizes his testimony.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: So that's not what I said.</p> <p>19 Q. (BY MS. NAGLE) But, Mr. Quick, you realize</p> <p>20 that Torrent isn't -- like, is not able to access all of</p> <p>21 the information regarding API that it sources?</p> <p>22 MR. DAVIS: Object to form. Objection,</p> <p>23 asked and answered.</p> <p>24 THE WITNESS: No, I'm not. But my point is</p> <p>25 that Torrent should have been able to understand exactly</p>
<p style="text-align: right;">Page 131</p> <p>1 reference in this report, I don't believe that they did</p> <p>2 an adequate chemical analysis.</p> <p>3 Q. Okay. And so I'm asking, well, if you believe</p> <p>4 it was inadequate, what would you have wanted them to</p> <p>5 do?</p> <p>6 A. Okay. As we -- if we can look at</p> <p>7 Paragraph 161, Torrent, as indicated, had they known of</p> <p>8 the chemicals used in the manufacturing process, the</p> <p>9 chemical analysis revealed what I said in there, had</p> <p>10 they done that, they would have been able to determine</p> <p>11 this. So they should -- they should have known what</p> <p>12 these chemicals were that were being used in the ZHP</p> <p>13 process.</p> <p>14 Q. So, Mr. Quick, you're aware that Torrent is a</p> <p>15 finish dose manufacturer, correct?</p> <p>16 A. Correct.</p> <p>17 Q. And as a finish dose manufacturer, you're aware</p> <p>18 that Torrent does not get full access to the DMF for</p> <p>19 valsartan API, correct?</p> <p>20 MR. DAVIS: Object to form. Object to</p> <p>21 mischaracterization of -- of the -- well, just object to</p> <p>22 form.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: So the point would be that I</p> <p>25 believe Torrent should thoroughly understand the process</p>	<p style="text-align: right;">Page 133</p> <p>1 how to process was, and they should have asked for a</p> <p>2 number of documents to be able to understand the</p> <p>3 situation. So when you say they're not able to, I think</p> <p>4 they should have been able to.</p> <p>5 Q. (BY MS. NAGLE) And how would you reconcile</p> <p>6 being able to do that if the information is proprietary</p> <p>7 information?</p> <p>8 A. Well, you ask -- you ask ZHP for it and you say</p> <p>9 we need this to do a thorough evaluation of ZHP as part</p> <p>10 of a supplier audit, supplier qualification. And I'm</p> <p>11 sure there were confidentiality agreements between</p> <p>12 Torrent and ZHP such as ZHP could have provided the</p> <p>13 information that Torrent would ask for.</p> <p>14 Q. Mr. Quick, you recognize that there's different</p> <p>15 testing done for API and for finish dose, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And so a chemist trained to do testing for</p> <p>18 finish dose wouldn't necessarily know how to do testing</p> <p>19 for API, correct?</p> <p>20 MR. DAVIS: Object -- object to the form.</p> <p>21 Calls for speculation. Incomplete hypothetical.</p> <p>22 You can answer it.</p> <p>23 THE WITNESS: I'm not even sure what you're</p> <p>24 trying to ask because it's not relevant. Maybe you can</p> <p>25 explain why you're asking that.</p>


<p style="text-align: right;">Page 134</p> <p>1 Q. (BY MS. NAGLE) Okay. Mr. Quick, I want to</p> <p>2 talk a little bit about your materials relied upon.</p> <p>3 So looking in Appendix A to your report, it</p> <p>4 looks like there are eight documents we see from Torrent</p> <p>5 and two deposition transcripts of Torrent employees. Do</p> <p>6 you see that?</p> <p>7 A. I see that.</p> <p>8 Q. And is this the totality of documents by</p> <p>9 Torrent you used in forming your opinions in your</p> <p>10 report?</p> <p>11 A. The documents that I used were the documents I</p> <p>12 reference in Exhibit A.</p> <p>13 Q. Okay. Any other documents?</p> <p>14 A. Not that I'm aware of.</p> <p>15 Q. In your report you also state that, (Reading:)</p> <p>16 The FDA also observed issues with Torrent's quality</p> <p>17 management activities related to the investigation of</p> <p>18 out-of-specification test results for their products and</p> <p>19 note that Torrent engaged Meridan consultants to assist,</p> <p>20 correct?</p> <p>21 MR. DAVIS: Can you refer to the paragraph,</p> <p>22 Brittany?</p> <p>23 Q. (BY MS. NAGLE) Sure. And that -- that's in</p> <p>24 Paragraph 163 to 166, the section I'm going to be</p> <p>25 talking about.</p>	<p style="text-align: right;">Page 136</p> <p>1 the only opinions. Were this to proceed to a merits</p> <p>2 report sometime in the future, I might offer different</p> <p>3 opinions. And if additional information became</p> <p>4 available, the opinions might differ. But again, it</p> <p>5 would apply to all users and all pills that were</p> <p>6 produced by the facility.</p> <p>7 Q. (BY MS. NAGLE) Okay. So as of right now</p> <p>8 understanding those caveats, the only opinions you're</p> <p>9 offering with respect to Torrent are the ones listed</p> <p>10 here in your report, Paragraphs 157 to 166 there?</p> <p>11 A. And again, that's -- that's true. And again,</p> <p>12 these were just examples.</p> <p>13 Q. Okay. So Mr. Quick, yesterday you were shown</p> <p>14 your notice of deposition that included some document</p> <p>15 requests. Do you remember that?</p> <p>16 A. I do.</p> <p>17 Q. And I don't think we entered these. But do</p> <p>18 you -- do you recall that your counsel served responses</p> <p>19 and objections in response to those document requests?</p> <p>20 A. I'm not -- I'm not certain what you're</p> <p>21 referring to.</p> <p>22 Q. Okay.</p> <p>23 A. We could pull that document up, if you'd like.</p> <p>24 MS. NAGLE: Sure. So can someone please</p> <p>25 pass the witness what's marked Tab 2 -- or Tab 1, I</p>
<p style="text-align: right;">Page 135</p> <p>1 A. So is the question I'm aware? Yes, I am aware.</p> <p>2 Q. Okay. And you note that Meridan found that 89</p> <p>3 of 157 out-of-specification investigations were</p> <p>4 non-compliant, right?</p> <p>5 A. That's correct.</p> <p>6 Q. Are you aware that none of those related to</p> <p>7 valsartan?</p> <p>8 A. I'm not sure what they were related to, but</p> <p>9 it's not relevant to the report. The issue was whether</p> <p>10 they were CGMP compliance.</p> <p>11 Q. Okay. So I guess taking a step back, the FDA</p> <p>12 warning letter that you're referring to is from</p> <p>13 October 2019, correct?</p> <p>14 A. That's correct.</p> <p>15 Q. So after the date of the recall?</p> <p>16 A. I'm assuming it's after the date of the recall.</p> <p>17 Q. Okay. Mr. Quick, are you offering any opinions</p> <p>18 about Torrent at this point outside of what's contained</p> <p>19 in your report?</p> <p>20 MR. DAVIS: Object -- object to form, vague</p> <p>21 and ambiguous.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: Okay. The only opinions I'm</p> <p>24 offering at this time relative to this declaration are</p> <p>25 the opinions that I express in this report. Those are</p>	<p style="text-align: right;">Page 137</p> <p>1 apologize, that I uploaded it on Exhibit Share.</p> <p>2 MR. DAVIS: Okay. Is this the -- the</p> <p>3 responses and objections that we served?</p> <p>4 MS. NAGLE: Yeah, that's correct.</p> <p>5 MR. DAVIS: Okay. I handing the --</p> <p>6 MR. MILLER: Brittney, this is Bill Miller,</p> <p>7 the tech. Do you need me to mark that in Exhibit Share?</p> <p>8 MS. NAGLE: Yes. Can you mark it? I</p> <p>9 believe we're up to 32, please.</p> <p>10 MR. MILLER: 32, yes. Do you need it up on</p> <p>11 the screen or just a paper copy?</p> <p>12 MS. NAGLE: I mean, paper copy is fine</p> <p>13 unless people on Zoom want to see it.</p> <p>14 (Exhibit No. 32 was marked.)</p> <p>15 MR. DAVIS: Do you -- do you want a few</p> <p>16 minutes to review it?</p> <p>17 THE WITNESS: Sure. I -- I'm not certain</p> <p>18 if I have seen this or not. I can review it if you'd</p> <p>19 like?</p> <p>20 MR. DAVIS: But there is no question</p> <p>21 pending.</p> <p>22 He's ready for your question, Brittney.</p> <p>23 Q. (BY MS. NAGLE) Okay. Mr. Quick, have you ever</p> <p>24 seen this document?</p> <p>25 A. I'm not certain whether I have or not. I've</p>

<p style="text-align: right;">Page 138</p> <p>1 seen a lot of documents. It's possible I may have seen 2 it. I don't believe so, but I could have. 3 Q. Okay. I'm going to represent to you that this 4 is the -- the formal response that your counsel made to 5 our -- to those document requests that you saw yesterday 6 and the notice of the deposition. Does that make sense? 7 A. That makes sense. 8 Q. Okay. And I want to direct your attention 9 to -- I think it's page 5 of the document. It's Request 10 No. 6 and the response to Request No. 6. 11 A. Okay. 12 Q. And Request No. 6 basically asks for the -- you 13 know, your complete and entire file for this case. And 14 it lays out some subcategories of documents. Do you see 15 that? 16 A. I see it. 17 Q. Okay. And in the response, it goes on to the 18 next page, your counsel says that they will produce a 19 list of documents that were provided to you in your 20 file. 21 MR. DAVIS: Is there a question? 22 Q. (BY MS. NAGLE) Do you see that? 23 A. Well, yeah, I can see that, yes. 24 Q. Okay. So can we look at Tab 2? 25 A. Tab 2.</p>	<p style="text-align: right;">Page 140</p> <p>1 your report. Do you understand? 2 A. I understand what you're saying. 3 Q. Okay. And 34 of 36 of those exhibits are 4 Torrent exhibits. Okay? 5 A. Okay. 6 Q. So you were sent more materials related to 7 Torrent than you ultimately relied upon, right? 8 MR. DAVIS: Object to -- object to form. 9 And object to failure to lay a proper predicate to the 10 question. 11 You can answer, though. 12 THE WITNESS: Yes, there are more documents 13 here. 14 Q. (BY MS. NAGLE) Okay. Do you know why these 15 additional documents were pro -- provided to you? 16 MR. DAVIS: I'm going to object. I'm going 17 to counsel the witness not to disclose attorney work 18 product and -- 19 But you can answer with that cautionary 20 instruction. 21 THE WITNESS: So I'd have to go back and 22 review each and every one of these to understand. So 23 I'm not certain just by looking at this list. 24 Q. (BY MS. NAGLE) Okay. So do you have any 25 reason why you chose not to rely on these documents that</p>
<p style="text-align: right;">Page 139</p> <p>1 MS. NAGLE: And can that be marked, please, 2 as Exhibit 33 or 34. 3 MR. DAVIS: Brittney, is this the list of 4 documents? 5 MS. NAGLE: Yeah. 6 MR. DAVIS: Okay. I'm handing it to the 7 court reporter. 8 (Exhibit No. 33 was marked.) 9 MR. DAVIS: The witness has the document, 10 Brittney. 11 Q. (BY MS. NAGLE) Okay. Mr. Quick, do you 12 recognize this document? 13 A. I'm not certain whether I've seen this document 14 or not before. 15 Q. Okay. So I'm going to represent to you that 16 this is the list of documents that your counsel provided 17 in response to Request No. 6 -- 18 A. Okay. 19 Q. -- about the complete file. Do you understand? 20 A. I understand. 21 Q. Okay. So I'm going to represent to you that if 22 you compare this list against the list in Exhibit A of 23 your report, the materials relied upon, there are 36 24 documents on that list you have that's marked, I 25 believe, Exhibit 33 that do not appear in Exhibit A of</p>	<p style="text-align: right;">Page 141</p> <p>1 were provided? 2 MR. DAVIS: Object to form. Same 3 instruction. 4 THE WITNESS: Well, my -- 5 MR. DAVIS: You can answer. 6 THE WITNESS: Okay. So I -- the documents 7 that I relied on for my report are the documents that I 8 reviewed and are Exhibit A. That's -- those are the 9 documents I relied on for my report. So there may have 10 been other documents that I didn't rely on these for my 11 report. 12 Q. (BY MS. NAGLE) Okay. And I'm just trying to 13 understand why -- why you excluded these 34 documents is 14 all. 15 A. Well, okay. So I cannot answer that question 16 without actually looking at those documents. But I'll 17 go back to the comments I made before. My report only 18 list examples. So there may be other examples that 19 would be in these documents which might be in a report 20 later, a merits report or something beyond that. But 21 the documents that I relied on for my report are the 22 documents that are in Exhibit A. So I'm not sure 23 specifically why these additional documents were not 24 relied on other than the fact I didn't need them 25 relative to providing the examples that I have in my</p>

<p style="text-align: right;">Page 142</p> <p>1 report.</p> <p>2 Q. Okay. So the additional documents found on --</p> <p>3 on this Exhibit 33 do not serve as a basis for any of</p> <p>4 the opinions contained in your report, correct?</p> <p>5 MR. DAVIS: Object to form.</p> <p>6 THE WITNESS: What I -- what I said was is</p> <p>7 that the documents that I relied on for my report are</p> <p>8 the ones that are Exhibit A.</p> <p>9 Q. (BY MS. NAGLE) Okay. So you're not relying on</p> <p>10 any of these additional documents found in this exhibit?</p> <p>11 A. If they're not in that Exhibit A, the answer is</p> <p>12 no.</p> <p>13 MS. NAGLE: Okay. I have no further</p> <p>14 questions for you, Mr. Quick. Thank you. I think one</p> <p>15 of my colleagues has some clean-up questions, but</p> <p>16 appreciate your time today. Thank you.</p> <p>17 THE WITNESS: All right. Thank you.</p> <p>18 MS. ISIDRO: I have just a few questions</p> <p>19 briefly.</p> <p>20 MR. DAVIS: Are you going to retread any</p> <p>21 ground or -- I don't think our protocol --</p> <p>22 MS. ISIDRO: It's just -- just some</p> <p>23 follow-up based on the question today.</p> <p>24 MR. DAVIS: I don't think our protocol is</p> <p>25 to have another bite at the apple here.</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. And some of those observations over the years</p> <p>2 related to issues about CGMP compliance?</p> <p>3 A. They did.</p> <p>4 Q. You testified that Baxter took the warning</p> <p>5 letter it received very seriously.</p> <p>6 A. Yes.</p> <p>7 MR. DAVIS: Asked and answered. Objection.</p> <p>8 This is covered in almost identically. You're just</p> <p>9 recovering the questions you asked yesterday.</p> <p>10 Q. (BY MS. ISIDRO) You, likewise, took any</p> <p>11 additional CGMP observations that were received over the</p> <p>12 years seriously?</p> <p>13 A. Yes.</p> <p>14 MR. DAVIS: Same objection. This is an</p> <p>15 utter waste of time. It's running out the clock.</p> <p>16 Q. (BY MS. ISIDRO) And you took appropriate</p> <p>17 corrective action?</p> <p>18 A. Yes.</p> <p>19 Q. In general, when Baxter received observations</p> <p>20 from the FDA related to CGMP issues, Baxter did not</p> <p>21 recall all product manufactured at the impact --</p> <p>22 impacted facilities, correct?</p> <p>23 MR. DAVIS: Object to form. Object to the</p> <p>24 extent it mischaracterizes his testimony from yesterday</p> <p>25 on which you asked these very questions. Objection,</p>
<p style="text-align: right;">Page 143</p> <p>1 MS. ISIDRO: It's just some brief follow-up</p> <p>2 based on the questions today.</p> <p>3 MR. DAVIS: You passed the witness</p> <p>4 yesterday. I -- I am going to place an objection to</p> <p>5 this.</p> <p>6 FURTHER EXAMINATION</p> <p>7 Q. (BY MS. ISIDRO) Mr. Quick, do you recall being</p> <p>8 asked some questions this morning regarding a warning</p> <p>9 letter that you had received at -- during your time at</p> <p>10 Baxter, warning letter received by Baxter during your</p> <p>11 time there?</p> <p>12 A. I do.</p> <p>13 MR. DAVIS: I'm objecting to this. You</p> <p>14 covered this yesterday. You don't get another bite at</p> <p>15 the apple. I'm sorry.</p> <p>16 MS. ISIDRO: We've noted your objection.</p> <p>17 Moving on.</p> <p>18 Q. (BY MS. ISIDRO) And in addition to the warning</p> <p>19 letter that was discussed, during your time at Baxter,</p> <p>20 there were other inspections by FDA which led to</p> <p>21 observations about the inspected facilities; is that</p> <p>22 right?</p> <p>23 A. Of the inspected facilities?</p> <p>24 Q. Yes.</p> <p>25 A. That's true, yes.</p>	<p style="text-align: right;">Page 145</p> <p>1 asked and answered.</p> <p>2 THE WITNESS: So Baxter recalled the</p> <p>3 products from the -- appropriately should have been</p> <p>4 recalled.</p> <p>5 Q. (BY MS. ISIDRO) But it did not recall every</p> <p>6 product from a particular facility every time that</p> <p>7 facility received a CGMP observation, correct?</p> <p>8 A. No. That's correct.</p> <p>9 MR. DAVIS: Same objection. I'm going to</p> <p>10 place a continuing objection to this. And this needs to</p> <p>11 be brief. This is -- you're recovering exactly what you</p> <p>12 covered yesterday. This is -- this is not proper.</p> <p>13 Q. (BY MS. ISIDRO) In general, when Baxter</p> <p>14 received observations from the FDA related to CGMP</p> <p>15 issues, Baxter did not stop releasing all product from</p> <p>16 that impacted facility to the market, correct?</p> <p>17 MR. DAVIS: Same objections.</p> <p>18 THE WITNESS: Well, it depends. In some</p> <p>19 cases that might have occurred.</p> <p>20 Q. (BY MS. ISIDRO) But it did not stop releasing</p> <p>21 all product from a particular facility every time that</p> <p>22 facility received any CGMP observation.</p> <p>23 A. Well, there are some cases where it might have.</p> <p>24 Q. But certainly not in every instance.</p> <p>25 A. Of course not.</p>

<p style="text-align: right;">Page 146</p> <p>1 MS. ISIDRO: I don't have any further 2 questions at this time. 3 MR. DAVIS: Okay. 4 MS. ISIDRO: Oh, and just briefly, I'd like 5 to mark for the record Exhibit -- I believe we're up 6 to 34. It is a thumb drive containing all of the 7 documents that were listed on Exhibit A to -- to 8 Mr. Quick's report as well as the written responses and 9 documents received in response to the notice of 10 deposition. 11 MR. DAVIS: That's two separate things. Is 12 that somehow -- I haven't seen how that's set forth on 13 the jump drive. 14 MS. ISIDRO: It's not separated, but we can 15 do that quickly and then mark it if that's -- if 16 that's -- we discussed it yesterday and you didn't 17 specify that, but I'm happy to do that now. 18 MR. DAVIS: I think maybe just for clarity 19 sake let's do it. 20 MS. ISIDRO: Separate it? 21 MR. DAVIS: Yeah. 22 MS. ISIDRO: Sure, no problem. 23 (Exhibit No. 34 was marked.) 24 MS. ISIDRO: And it will be Exhibit 34, 25 correct?</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. Some of those documents are listed in Exhibit A 2 to your report or -- or in plaintiff's responses to the 3 Request No. 6 that Ms. Nagle mentioned a few minutes 4 ago, correct? 5 A. Correct. 6 Q. And then there's some amount of documents that 7 were also shown you over the past couple of days that 8 are not referenced in your report or in those responses, 9 correct? 10 A. That's correct. 11 Q. Okay. Based on your review of those documents, 12 is there anything in them that changes your core opinion 13 in this declaration that appears at Paragraph 191 of 14 your declaration? 15 MS. NAGLE: Object to form. 16 THE WITNESS: There is nothing in those 17 documents that would change my opinion in 191. 18 Q. (BY MR. DAVIS) Okay. And what is that opinion 19 in Paragraph 191? 20 A. I'll read it. It says, (Reading:) I do 21 conclude that because of the nature of these 22 deficiencies being high level corporate QA failings, the 23 corporate quality assurance deficiencies described 24 herein are the type of quality assurance activities that 25 would have impacted each of the manufactures defendants'</p>
<p style="text-align: right;">Page 147</p> <p>1 MR. DAVIS: Yeah, 34 and then 30 -- 2 yeah, 34. I mean, yeah, it can all be on that same jump 3 drive, yeah. 4 MS. ISIDRO: We'll put it in two separate 5 folders. 6 MR. DAVIS: Folders, yeah. Okay. No 7 objection. 8 MR. KERNER: Anybody else on the Zoom have 9 any questions? 10 MR. DAVIS: Okay. Not hearing anything, 11 why don't we take like a one-minute break just to see 12 how much time is left. 13 VIDEOGRAPHER: Off the record. The time 14 is 12:01 p m. 15 (Brief recess.) 16 VIDEOGRAPHER: Back on the record. The 17 time is 12:03 p m. 18 EXAMINATION 19 Q. (BY MR. DAVIS) Mr. Quick, the defendants have 20 passed the witness after all questioning you for some 21 amount of time. I just have a few redirect questions on 22 my end. 23 So over the course of the past two days, 24 you were shown a number of documents, correct? 25 A. Correct.</p>	<p style="text-align: right;">Page 149</p> <p>1 valsartan products equally and in the same manner. 2 Q. Okay. Thank you. Are you -- you're familiar 3 that this litigation that you're testifying in today is 4 part of what's called a multi-district litigation 5 involving all these manufacture defendants whose 6 attorneys questioned you today? 7 A. I am. 8 Q. Okay. 9 MR. ABRAHAM: John, this is Eric. I'm just 10 going to place an objection on the record to the leading 11 nature of your questions. It's improper. 12 MR. DAVIS: Thank you for the speaking 13 objection, Eric and I'm allowed to do this for the 14 introduction matters. 15 MR. ABRAHAM: Right. That's why I let it 16 go for the first couple of questions. Your last 17 question was improper. 18 MR. DAVIS: This is an introductory matter, 19 Eric. Thank you. 20 MR. ABRAHAM: I move to strike the last 21 answer and the last question. 22 MR. DAVIS: The judge has told us, the 23 parties, numerous times, Eric, that he will not tolerate 24 motions to strike as part of these depositions. So 25 that's -- that's not proper. Okay.</p>

<p style="text-align: right;">Page 150</p> <p>1 MR. ABRAHAM: Right. He's also said no</p> <p>2 leading questions of your own witness. So you follow</p> <p>3 the rule, I'll follow the rule.</p> <p>4 MR. DAVIS: Thank you.</p> <p>5 Q. (BY MR. DAVIS) So Mr. Quick, what's your</p> <p>6 understanding of why these manufacture defendants are a</p> <p>7 part of this litigation?</p> <p>8 MS. ISIDRO: Objection.</p> <p>9 MR. ABRAHAM: Objection, form. No</p> <p>10 foundation.</p> <p>11 MR. DAVIS: Let's not have multiple</p> <p>12 attorneys objecting. I think -- I think Nilda has it</p> <p>13 covered. She's present.</p> <p>14 Q. (BY MR. DAVIS) okay. So what's your</p> <p>15 understanding, sir, of why these defendants are</p> <p>16 defendants in this litigation?</p> <p>17 A. Because of the presence of nitrosamines in the</p> <p>18 finished drug products.</p> <p>19 Q. Okay. And does the -- does the presence of</p> <p>20 those contaminants, nitrosamines as you said, is that</p> <p>21 one component of your opinion in Paragraph 28 of your</p> <p>22 declaration --</p> <p>23 MS. ISIDRO: Objection, form.</p> <p>24 Q. (BY MR. DAVIS) -- that the finished drug</p> <p>25 products involved in this litigation manufactured by the</p>	<p style="text-align: right;">Page 152</p> <p>1 deposition of John Quick. Off the record at 12:08 p.m.</p> <p>2 (Proceedings concluded at 12:09 p.m.)</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 151</p> <p>1 defendants are adulterated?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Okay. Your -- your report has a number</p> <p>4 of exemplary sort of what you describe as examples of</p> <p>5 corporate level CGMP failures, in your words, that you</p> <p>6 provide as to each of the manufacture defendants; is</p> <p>7 that right?</p> <p>8 A. That's right.</p> <p>9 Q. Okay. How long have you been in the</p> <p>10 pharmaceutical and -- and general sort of FDA medical</p> <p>11 device industry, sir?</p> <p>12 MS. ISIDRO: Objection.</p> <p>13 THE WITNESS: Over 55 years.</p> <p>14 Q. (BY MR. DAVIS) Okay. And your -- your</p> <p>15 observations in this declaration, are they based only on</p> <p>16 the documents and other materials or are they also based</p> <p>17 on those 55 years of experience that you have?</p> <p>18 MS. ISIDRO: Objection, form.</p> <p>19 THE WITNESS: They are based on my</p> <p>20 experience in addition to the documents.</p> <p>21 MR. DAVIS: Thank you. No further</p> <p>22 questions.</p> <p>23 Okay. Hearing nothing else, I think we can</p> <p>24 wrap it up and go off the record.</p> <p>25 VIDEOGRAPHER: Okay. This concludes the</p>	<p style="text-align: right;">Page 153</p> <p>1 REPORTER'S CERTIFICATION</p> <p>2 DEPOSITION OF JOHN QUICK</p> <p>3 VOLUME 2 OF 2</p> <p>4 TAKEN JANUARY 28, 2022</p> <p>5 I, Janalyn Elkins, Certified Shorthand</p> <p>6 Reporter in and for the State of Texas, hereby certify</p> <p>7 to the following:</p> <p>8 That the witness, JOHN QUICK, was duly sworn</p> <p>9 by the officer and that the transcript of the oral</p> <p>10 deposition is a true record of the testimony given by</p> <p>11 the witness;</p> <p>12 That the original deposition was delivered to</p> <p>13 MS. NILDA ISIDRO;</p> <p>14 That a copy of this certificate was served on</p> <p>15 all parties and/or the witness shown herein on</p> <p>16 _____.</p> <p>17 I further certify that pursuant to FRCP No.</p> <p>18 30(f)(i) that the signature of the deponent was</p> <p>19 requested by the deponent or a party before the</p> <p>20 completion of the deposition and that the signature is</p> <p>21 to be returned within 30 days from date of receipt of</p> <p>22 the transcript. If returned, the attached Changes and</p> <p>23 Signature Page contains any changes and the reasons</p> <p>24 therefor.</p> <p>25 I further certify that I am neither counsel</p> <p>for, related to, nor employed by any of the parties in</p>

<p style="text-align: right;">Page 154</p> <p>1 the action in which this proceeding was taken, and</p> <p>2 further that I am not financially or otherwise</p> <p>3 interested in the outcome of the action.</p> <p>4 Certified to by me this 6th day of February</p> <p>5 2022.</p> <p>6</p> <p>7 </p> <p>8 JAINALYN ELKINS</p> <p>9 Texas CSR 3631</p> <p>10 Expiration Date 1/31/2023</p> <p>11 Veritext Legal Solutions</p> <p>12 300 Throckmorton Street, Suite 1600</p> <p>13 Fort Worth, Texas 76102</p> <p>14 Firm Registration No. 571</p> <p>15 PH: (817) 336-3042</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 156</p> <p>1 In Re: Valsartan, Losartan, Et Al v.</p> <p>2 John Quick (#5063421)</p> <p>3 ERRATA SHEET</p> <p>4 PAGE _____ LINE _____ CHANGE _____</p> <p>5 _____</p> <p>6 REASON _____</p> <p>7 PAGE _____ LINE _____ CHANGE _____</p> <p>8 _____</p> <p>9 REASON _____</p> <p>10 PAGE _____ LINE _____ CHANGE _____</p> <p>11 _____</p> <p>12 REASON _____</p> <p>13 PAGE _____ LINE _____ CHANGE _____</p> <p>14 _____</p> <p>15 REASON _____</p> <p>16 PAGE _____ LINE _____ CHANGE _____</p> <p>17 _____</p> <p>18 REASON _____</p> <p>19 PAGE _____ LINE _____ CHANGE _____</p> <p>20 _____</p> <p>21 REASON _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 John Quick Date _____</p> <p>25</p>
<p style="text-align: right;">Page 155</p> <p>1 John R. Davis</p> <p>2 jdavis@slackdavis.com</p> <p>3 February 7, 2022</p> <p>4 RE: In Re: Valsartan, Losartan, Et Al v.</p> <p>5 1/28/2022, John Quick (#5063421)</p> <p>6 The above-referenced transcript is available for</p> <p>7 review.</p> <p>8 Within the applicable timeframe, the witness should</p> <p>9 read the testimony to verify its accuracy. If there are</p> <p>10 any changes, the witness should note those with the</p> <p>11 reason, on the attached Errata Sheet.</p> <p>12 The witness should sign the Acknowledgment of</p> <p>13 Deponent and Errata and return to the deposing attorney.</p> <p>14 Copies should be sent to all counsel, and to Veritext at</p> <p>15 erratas-cs@veritext.com</p> <p>16</p> <p>17 Return completed errata within 30 days from</p> <p>18 receipt of testimony.</p> <p>19 If the witness fails to do so within the time</p> <p>20 allotted, the transcript may be used as if signed.</p> <p>21</p> <p>22 Yours,</p> <p>23 Veritext Legal Solutions</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 157</p> <p>1 In Re: Valsartan, Losartan, Et Al v.</p> <p>2 John Quick (#5063421)</p> <p>3 ACKNOWLEDGEMENT OF DEPONENT</p> <p>4 I, John Quick, do hereby declare that I</p> <p>5 have read the foregoing transcript, I have made any</p> <p>6 corrections, additions, or changes I deemed necessary as</p> <p>7 noted above to be appended hereto, and that the same is</p> <p>8 a true, correct and complete transcript of the testimony</p> <p>9 given by me.</p> <p>10 _____</p> <p>11 _____</p> <p>12 John Quick Date _____</p> <p>13 *If notary is required</p> <p>14 SUBSCRIBED AND SWORN TO BEFORE ME THIS</p> <p>15 _____ DAY OF _____, 20____.</p> <p>16</p> <p>17</p> <p>18 _____</p> <p>19 NOTARY PUBLIC</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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[witness - zoom]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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1 In Re: Valsartan, Losartan, Et Al
2 John Quick (#5025079)

ACKNOWLEDGEMENT OF DEPONENT

3
4 I, John Quick, do hereby declare that I
5 have read the foregoing transcript, I have made any
6 corrections, additions, or changes I deemed necessary as
7 noted above to be appended hereto, and that the same is
8 a true, correct and complete transcript of the testimony
9 given by me.

10
11 
12 John Quick

21/18/22
13 Date

14 *If notary is required

15 SUBSCRIBED AND SWORN TO BEFORE ME THIS
16 18 DAY OF February, 20 22.

17
18 
19 NOTARY PUBLIC

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NOTARY PUBLIC, STATE OF ILLINOIS
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1 In Re: Valsartan, Losartan, Et Al

2 John Quick (#5025079)

3 E R R A T A S H E E T

4 PAGE 17 LINE 7 CHANGE EMPLOYEE SHOULD BE
5 EMPLOYER6 REASON CORRECTION7 PAGE 17 LINE 9 CHANGE "IN AN EMPLOY" SHOULD
8 BGE "AN EMPLOYEE"9 REASON CORRECTION

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18 REASON _____

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21 REASON _____22
23
24 John Quick

Date

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1 In Re: Valsartan, Losartan, Et Al v.

2 John Quick (#5063421)

3 ACKNOWLEDGEMENT OF DEPONENT

4 I, John Quick, do hereby declare that I
5 have read the foregoing transcript, I have made any
6 corrections, additions, or changes I deemed necessary as
7 noted above to be appended hereto, and that the same is
8 a true, correct and complete transcript of the testimony
9 given by me.

10 

11
12 John Quick

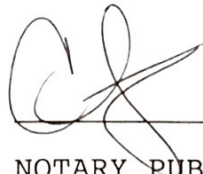
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1 In Re: Valsartan, Losartan, Et Al v.

2 John Quick (#5063421)

3 E R R A T A S H E E T

4 PAGE 63 LINE 15 CHANGE ESTABLISHED5 SHOULD BE ESTABLISHMENT6 REASON COURT REPORTER MISSED THIS

7 PAGE _____ LINE _____ CHANGE _____

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9 REASON _____

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21 REASON _____22
23
24 John Quick

Date

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1 In Re: Valsartan, Losartan, Et Al

2 John Quick (#5025079)

3 E R R A T A S H E E T

4 PAGE 11 LINE N/A CHANGE Exhibit #18 in the
5 glossary should be the Deposition of Pan Lin as
6 correctly noted at 225:4 and on the exhibit
7 itself.

8
9 REASON _____

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25 /s/ Nilda Isidro

3/10/22